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Clinical laboratory improvement
act of 1978

CLINICAL LABORATORY IMPROVEMENT ACT OF 1978

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS

HOUSE OF REPRESENTATIVES

NINETY-FIFTH CONGRESS

SECOND SESSION

ON

H.R. 10909

TO AMEND THE PUBLIC HEALTH SERVICE ACT TO REVISE AND STRENGTHEN THE PROGRAM UNDER THAT ACT FOR NATIONAL STANDARDS FOR AND LICENSING OF CLINICAL LABORATORIES, TO AMEND THE SOCIAL SECURITY ACT TO REQUIRE LABORATORIES PROVIDING SERVICES FINANCED UNDER TITLES XVIII AND XIX OF SUCH ACT TO MEET THE REQUIREMENTS OF SUCH PROGRAM, AND FOR OTHER PURPOSES

MAY 9, 1978

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H.R. 10909, CLINICAL LABORATORY IMPROVEMENT ACT OF 1978

TUESDAY, MAY 9, 1978

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON WAYS AND MEANS,
Washington, D.C.

The subcommittee met at 8:07 a.m., pursuant to notice, in room H–137, the Capitol, Hon. Dan Rostenkowski (chairman of the subcommittee) presiding.

Mr. ROSTENKOWSKI. Good morning, ladies and gentlemen.

The purpose of our hearing this morning is to receive testimony concerning the impact of H.R. 10909, the Clinical Laboratory Improvement Act of 1978, on the medicare program.

Under present law, the existence of several laboratory review authorities has given rise to overlapping and occasionally duplicative standards and inspections. There is general agreement, therefore, on the need to bring about uniformity and consistency in the application of laboratory standards.

In addition, problems have come to light concerning billing practices with respect to laboratory services under medicare and medicaid. The bill also addresses these problems by providing for certain changes in billing requirements under these programs.

The subcommittee is interested in receiving testimony relevant to these issues and the effectiveness of H.R. 10909 in resolving them.

[The opening statement of Mr. Duncan follows:]

INTRODUCTORY REMARKS OF HON. JOHN J. DUNCAN

Mr. Chairman, I would like to take this opportunity to welcome the witnesses who will testify before us today on this important legislation, which has been referred to the Ways and Means Committee after having been reported by our colleagues on the Committee on Interstate and Foreign Commerce.

The growth of the clinical laboratory industry, in terms of number of providers and dollars involved, has mushroomed in recent years. Virtually all Americans are likely to require the services, at one time or another, of clinical laboratories. They understandably expect, and properly demand, that tests to diagnose or treat their illnesses are performed as accurately as possible, by trained and competent personnel. Although the scope of this legislation extends beyond the laboratories performing only tests paid for with government funds, its impact on the cost and quality of the services provided by government programs—particularly Medicare—is enormous.

We have before us a bill that would enable HEW to regulate, in an unprecedented manner, both interstate and intrastate laboratories. More than 13,000 hospital and independent laboratories are potentially subject to regulation. I believe it is important that we do our part to ensure that any such extension of federal regulatory authority would prove to be cost-effective, and would protect the medical needs, constitutional rights, and other legitimate interests of all our citizens—patients and providers alike.

Mr. Chairman, I look forward to hearing from our witnesses, and to our acting promptly with respect to this legislation.

Mr. ROSTENKOWSKI. Our first witness this morning is Mr. Robert A. Derzon, Administrator of the Health Care Financing Administration, who will be testifying on behalf of the Department of Health, Education, and Welfare.

Mr. Derzon.

STATEMENT OF ROBERT DERZON, ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ACCOMPANIED BY JOYCE LASHOF, DEPUTY ASSISTANT SECRETARY FOR HEALTH PROGRAMS AND CAROL EMMOTT, SPECIAL ASSISTANT, OFFICE OF THE DEPUTY ASSISTANT SECRETARY FOR LEGISLATION (HEALTH)

Mr. DERZON. Thank you, Mr. Chairman and members of the committee.

It is my pleasure to be here this morning. With me is Dr. Joyce Lashof, Deputy Assistant Secretary of Health, representing the Public Health Service, and Dr. Carol Emmott, Special Assistant in the Office of the Assistant Secretary for Legislation.

As you know, the laboratory activities in Government tend to intersect between the two of us, the Health Care Financing Administration and the Public Health Service. We are here this morning to support the bill, H.R. 10909, the Clinical Laboratory Improvement Act of 1978. We have a prepared statement which I would like to have submitted for the record, and then I would like to make just a few comments on our testimony.

Mr. ROSTENKOWSKI. Without objection, your entire statement will be included in the record.

Mr. DERZON. First, by way of background, laboratory work in the United States is a critically important part of the health care delivery system and the health care financing system. It is a large activity dollarwise and involves many laboratories, large and small, working independently of hospitals as well as in hospitals. It represents approximately one-tenth of the total health expenditures in the United States currently.

The Clinical Laboratory Improvement Act is principally concerned with improving the quality of performance of clinical laboratory services on behalf of all American patients, and of course in our particular interest, medicare and medicaid beneficiaries.

At the present time we are working under existing legislation that allows for multiple sets of standards to be set for laboratory work. One of the advantages of this bill is that it makes a genuine effort to unify through a single standard various duplicative mechanisms with respect to the certification of laboratory services.

The bill also addresses physician billing for laboratory services, a critically important area to the medicare program. We have been concerned, as has been this committee from time to time, with abusive practices, particularly with regard to independent laboratory services, where a physician sends specimens to an outside laboratory and then

those specimen results are returned to the physician. The physicians in some cases have added substantial markups to the bills for these laboratory services. This practice, of course, is considered improper by the American Medical Association and other responsible physician groups.

The bill attempts to stop this abuse by requiring the physician to indicate on the bill whether the service was performed by an outside laboratory, and if so, the amount charged to him by the laboratory. Medicare would then pay the reasonable charge for the laboratory service, or if it turns out to be less, the amount the laboratory charged the physician.

The program, of course, would continue to recognize a nominal charge for the physician's cost of collecting and handling the sample where such charges are customary.

If the physician failed to provide the necessary information on the billing forms, medicare would pay on the basis of the lowest amount charged by the laboratory in that locality for tests performed on behalf of physicians. That represents a change in current practice.

There are disadvantages with this particular provision, but in our view it is the best possible provision at the present time. The basic advantage, of course, is that it seems to be the most practical way at present that physicians can continue to bill for services performed by others in the program. Of course, there are some advantages in terms of simplified billing practices between the laboratories and the physicians in this approach.

The bill calls for a study on the effect of this provision, and particularly on whether or not the patients benefit under this provision in terms of lower laboratory costs.

There are certain technical amendments that are needed in this section to clarify what amounts will be allowed when taking into consideration the medicare cost sharing arrangements, and we would like to submit those, if we have an opportunity.

Among the other provisions of the bill are ones to phase the new program in over a reasonable period of time. This program represents a substantial increase in the governmental activities in terms of regulating laboratory standards throughout the United States, and this bill does provide for phase-in time, particularly for rural laboratory services. We generally applaud those provisions and think they are important.

I should reiterate here that the Public Health Service and the Health Care Financing Administration are the two arms of HEW that are principally involved in management of laboratory standards for the Government. We have now, and have had for the past year, a working agreement—memorandum of understanding—which essentially divides the work up sensibly among the two parties. We feel we have an operation which historically has been troublesome within HEW, but which is now smoothing out. We believe that the mechanisms in place inside HEW are sufficient to bring the best resources to bear from wherever they are in HEW on laboratory problems. Therefore, we have been opposed to setting up separate or new organizations within HEW, more reorganization, which we don't feel is necessary.

There are some who question the effectiveness of this interagency agreement, but in our view we believe that we have made significant progress through this approach and would like to continue it.

With respect to monitoring, this bill has significant implications in terms of providing adequate monitoring and enforcement of laboratories. One of the historic problems in the management of laboratories around the country has been a substantial level of inaccuracy in laboratory work. Testing was done, through blind testing in some cases, and it was found that many laboratories were not consistent in providing quality laboratory results.

We want to make sure that this bill has adequate monitoring provisions, and we have a feeling that it does need to be slightly strengthened. We are finding out, as CDC expands its monitoring activities under our memorandum of understanding, that certain laboratories have been denying admittance to the laboratory to our CDC inspectors. We want to make sure that the laboratories under the jurisdiction of this act have their doors open to assessment and monitoring.

We expect it to be constructive and helpful. We think it is important.

We also think that, given the scope of the studies that are required under this bill, it would be very important to get into all laboratories so that we can do the studies which Congress is asking us to do in this bill.

With respect to the rural laboratories, just a brief comment. We think some further modification may be necessary to better coordinate the language of this bill with the Rural Health Clinics Act. That act provides for laboratory services within rural health clinics. What is required are technical adjustments to this bill to make it consistent with the rural health clinics bill.

On proficiency testing, we are pleased that the bill authorizes us to use blind testing, but we want to caution that blind testing on a large-scale basis does have limitations. It can be used selectively and is important as a tool, but we know that it has certain shortcomings, and that it could be difficult to impose through a total proficiency testing system.

Lastly, we have some concerns with respect to the disclosure of information in the health systems agency provisions under this act; however, we feel that we can work those out with the Commerce Committee. As you know, that committee has been considering the Planning Act and can straighten out what we believe are minor inconsistencies in the two pieces of legislation.

I want to assure the committee that the Department strongly supports this bill, and that we think it will be an important step toward improving the laboratory services in the United States on behalf of our beneficiaries.

That concludes our opening comments.

[The prepared statement follows:]

STATEMENT OF ROBERT DERZON, ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION

Mr. Chairman, Dr. Joyce Lashof, Deputy Assistant Secretary for Health Programs, has joined me today to discuss the Department's views on H.R. 10909, the Clinical Laboratory Improvement Act of 1978. The Department is committed to assuring high quality in clinical laboratory services and to preventing fraud and abuse in the reimbursement for such services. We strongly support the intent of

this bill to provide for uniformity in the development and application of standards for clinical laboratories. We urge your favorable consideration of H.R. 10909 and support for those provisions which would amend or affect provisions of the Medicare law.

BACKGROUND

Mr. Chairman, as you are well aware, clinical laboratory services are a significant part of the nation's health care system. Over five billion laboratory tests are performed annually at a total cost of around $12 billion, about 10 percent of our annual national cost of health care. The importance of these tests in the assessment of health and in the diagnosis, treatment and monitoring of disease demands efficient, careful safeguards to assure the highest quality of the results.

H.R. 10909 seeks to improve the performance of clinical laboratories by providing for uniform and upgraded standards for virtually all categories of laboratories. Under the existing laws there are essentially three sets of standards being applied to laboratories under Medicare: (1) standards of the Joint Commission on Accreditation of Hospitals (JCAH) and the American Osteopathic Association (AOA), (2) Medicare hospital regulations for non-JCAH or non-AOA accredited hospitals, and (3) the Medicare regulations for laboratories operating independently of hospitals. We are also regulating interstate laboratories under the authority of the Clinical Laboratory Improvement Act of 1967 (CLIA '67.) These varied authorities are confusing, duplicative, costly and sometimes inequitable. We support H.R. 10909 because we believe this legislation will correct these deficiencies.

We would like to begin this morning by calling to your attention several aspects of Title II of this bill that we think merit attention.

PHYSICIAN BILLINGS

Mr. Chairman, one of the most troublesome and costly abuses that we find in Medicare reimbursement for laboratory services arises from the practice of some physicians of adding to their bills substantial markups for services performed by an outside laboratory. This practice is, I should add, considered improper by the American Medical Association.

H.R. 10909 seeks to stop this abuse by requiring the physician to indicate on the bill whether the service was performed by a laboratory outside his office, and if so, the amount charged by such laboratory. Medicare would then pay the reasonable charge for the laboratory services, or if less, the amount that the laboratory charged the physician. The program would, of course, continue to recognize a nominal charge for the physician's cost of collecting and handling the sample, where such charges are customary. If the physician fails to provide the necessary information, Medicare would pay on the basis of the lowest amount charged by the laboratories in that locality for tests performed for physicians.

In developing this provision both the Subcommittee on Health of the Committee on Interstate and Foreign Commerce and the Department recognized as a major disadvantage the potential for a physician to continue to markup charges for purchased laboratory services, and to bill Medicare beneficiaries directly for the amounts disallowed by the program. However, no alternative was found that did not involve prohibiting a physician from charging a beneficiary for a service actually performed by a laboratory.

The bill does call for a study of the effects of this provision, particularly in regard to how frequently the disallowed markups are imposed on the beneficiary. We believe that the provision represents a practical approach to dealing with the markup abuse, pending the findings of the study. It will also facilitate coordination of Medicare-Medicaid reimbursement practices with regard to laboratory services. However, certain technical amendments are needed to clarify that the allowed amounts are to take into account the Medicare cost sharing requirements.

PHASING-IN OF NEW PROGRAMS

The provisions regarding reimbursements will go a long way to tighten this part of the Medicare program. Equally important, though, is the imposition of a single set of standards on all laboratories subject to Federal regulation. While this uniformity represents a significant change from existing requirements, we believe H.R. 10909 is a practical tool that can be used to improve laboratory services in a realistic manner.

First, the bill provides for a gradual phasing-in of the application of the national standards to intrastate laboratories. These laboratories would not be required to comply with the national standards (or the State standards where a State has primary enforcement responsibility) until 3 years from the date of enactment. Laboratories in rural areas would have an additional 2-year exemption from compliance with supervisory and technical personnel standards, in recognition of their need for additional time to meet the new requirements.

Second, in administering the new provisions, the Secretary could continue to use the State agencies now conducting Medicare surveys under agreements with the Department. The Secretary and the State which has primary enforcement responsibility also can use qualified public or nonprofit private entities (such as College of American Pathologists (CAP) and JCAH) for laboratory inspections if these entities have adopted standards at least as stringent as the national standards. We believe that these phasing-in provisions are reasonable and realistic, and that they would ease the transition between the current Medicare laboratory standards program and the new program.

DEPARTMENTAL COORDINATION

Two major steps have been taken within the Department to coordinate activities in the clinical laboratory area. First, we are continuing to move ahead with full implementation of the Interagency Agreement for the Regulation and Improvement of Clinical Laboratories. That Agreement provides for a reasonable separation of roles along functional lines with the Public Health Service (PHS) through the Center for Disease Control (CDC) having primary responsibility in professional scientific and technical areas and with the Health Care Financing Administration (HCFA) having primary responsibility for regulatory and administrative areas. HCFA, through designed State agencies, is presently conducting onsite inspection for the initial and continued assessment of all clinical laboratories participating in the Medicare/Medicaid program and the interstate laboratory program.

Second, HCFA and the PHS have each designed focal points for all clinical laboratory activities. I have organized all clinical laboratory activities in HCFA under the Health Standards and Quality Bureau (HSQB), and the Office of Health Practice Assessment (OHPA) under Dr. Lashof has been designated as the PHS focal point. The PHS Task Force on Clinical Laboratories has also been established for the purpose of assisting in the developing of PHS policy and providing scientific and technical advice on clinical laboratory matters. The Task Force has representatives from all PHS agencies concerned with clinical laboratories, and is working closely with HCFA in the development of Departmental policy and regulations in this area.

I understand that some questions have been raised as to the effectiveness of the Interagency Agreement and these new departmental arrangements. We have found the agreement to be an effective mechanism for expediting the identification and resolution of a number of major issues and feel it represents the best means of utilizing the resources of the Department which must inevitably be involved in the regulation of clinical laboratories.

Under the Interagency Agreement, CDC has provided HCFA with technical assistance in the areas of training, quality control, personnel requirements and proficiency testing, and with revised quality control checklists or survey report forms, which should lead to an improved evaluation methodology.

The PHS has been responsive to our requests for policy guidance and for scientific and technical advice, and is providing input on topics such as: competency examinations for clinical laboratory technologists, regulations for personnel requirements for clinical laboratories, a model proficiency testing program, the JCAH Standards for Pathology and Medical Laboratory Services, and quality control standards and inspection mechanisms. In addition, PHS and HCFA are already preparing an implementation plan for CLIA 1978.

This strong support and cooperation between agencies is one of the reasons we believe we can implement H.R. 10909 effectively. We are pleased that the bill, as reported by the Commerce Committee, now grants the Secretary maximum flexibility in the management of the internal operating components that will conduct these critical laboratory inspections and evaluations. We believe the Department's commitment to a uniform laboratory program is beginning to yield positive results, and that under this legislation, these results will continue and improve.

However, there are clarifying amendments to Title I of the bill which we believe will assist us in carrying out our laboratory program. We will discuss these briefly here and will be consulting with the Commerce Committee to elicit its support for needed changes.

MONITORING

Mr. Chairman, we are pleased that the recent report by the Committee on Interstate and Foreign Commerce clarified that "for purposes of determining whether States with primary enforcement continue to meet requirements for primary enforcement responsibility, the Secretary may designate individuals to conduct inspections of laboratories to determine if they are in compliance with applicable State standards." As we stated in testimony last June, however, we believe the Secretary also should have specific authorization to monitor the programs and evaluate the application of national standards by States that do not have primary enforcement responsibility as well as to evaluate the application of standards by private groups whose programs are found to be equivalent to the national standards.

Under CLIA 1967, the standards and inspection activities of the College of American Pathologists' "special program" and the New York laboratory licensure program have been found to be equivalent to the clinical laboratory evaluation program which the Department has conducted under the interstate program. CDC routinely monitors the performance of these two surrogate programs, and the partial programs of seven States which act as agents of the Secretary for certain parts of the CLIA program. The Interagency Agreement provides for CDC to extend this monitoring to all approved State programs and other private surrogate programs, such as the JCAH or the CAP, in order to objectively determine whether these evaluation programs are applying the Federal standards (Medicare/Medicaid, and CLIA 1967) or equivalent standards.

Although we had called for such explicit monitoring authority while this legislation was under consideration in the Commerce Committee, CDC had not yet begun to implement this portion of the agreement. Since its consideration in the Commerce Committee, CDC has begun monitoring these additional laboratories and has been denied admittance to laboratories on several occasions.

Mr. Chairman, we believe that it is critical that H.R. 10909 clearly authorize continuation of this independent assessment, through monitoring, of all surrogate programs so that the Secretary can carry out his responsibility under this legislation to assure consistent performance by clinical laboratories of accurate and reliable tests and procedures. Equally important in implementing this legislation is the provision of authority to obtain from the laboratories the information necessary to complete the numerous studies required by the legislation. Such information may include submission of written materials by the laboratory or on-site data collection by an individual designated by the Secretary. We are discussing this problem with the Commerce Committee to urge their support of an amendment that would clearly authorize this critical monitoring function.

RURAL LABORATORIES

H.R. 10909 presently includes language providing an exemption for laboratories located in physician offices and in rural areas. We believe that these provisions as currently drafted are appropriate. However, the recently enacted Rural Health Clinic Services Act (Public Law 95-210), provides that each rural health clinic must provide routine diagnostic laboratory services and that, for purposes of meeting health and safety standards under Medicare, a rural clinic's laboratory is to be treated the same way as a laboratory in a physician's office.

We are concerned about potential program inconsistencies which may develop in implementing the Rural Health Clinic provisions and the provisions of this bill. We believe that by including the rural health clinic laboratories in the physician office study authorized by Section 103, we will be able to evaluate such facilities and make recommendations for the appropriate conditions for their exemption.

PROFICIENCY TESTING

H.R. 10909 would require that proficiency testing standards include provisions for annual on-site testing, and would also allow inclusion of "blind" testing. Mr. Chairman, we are pleased that the bill authorizes but does not require "blind" testing. The cost and logistics involved and the fact that laboratories may have

means of identifying the source of the specimen, make "blind" testing impractical except on a limited basis. Proficiency testing is one of the areas in which we believe qualified public or non-profit private entities will have an important role. However, we are confident that the Congress does not intend that such an entity must be able to provide a complete proficiency testing program in order to enter into an agreement with the Secretary or any State to administer proficiency tests. These agreements should provide flexibility enough for such entities to administer all or portions of a proficiency testing program.

HEALTH SYSTEMS AGENCIES

Section 373 would require laboratories to submit to both the local health systems agency (HSA) and the Secretary an itemized schedule of all current rates charged for services and information on any contractual arrangements between the laboratories and physicians or other health providers. The HSA would, however, be prohibited from disclosing either the identity of any person for whom the laboratory performed services or from disclosing information on contractual relationships, except to appropriate Federal or State officials or in connection with enforcement of this Act or of criminal laws. However, the National Health Planning and Resources Development Act (Public Law 93–641) requires that all records and data be made available, upon request, to the public. This provision is intended to insure that HSAs remain the publicly accountable entities envisioned by Congress. We intend to discuss this apparent conflict with the Commerce Committee to achieve the most effective solution.

CONCLUSION

In conclusion, Mr. Chairman, the Department believes that, with limited clarifying amendments, H.R. 10909 now represents a sound approach to program improvement. We welcome the opportunity to work with this Subcommittee to further refine H.R. 10909 so that jointly we can achieve the best possible authorization for a uniform, and administratively efficient regulatory program for clinical laboratories.

Mr. ROSTENKOWSKI. Thank you, Mr. Derzon.

Mr. Derzon, the provision in the bill that requires a reduction in each laboratory charge for commissions and rental payments seems to me to present great administrative difficulties for really little purpose. What is the Department's position on that?

Mr. DERZON. That provision in the bill as it is currently written would provide some administrative problems. I think the intent of the provision is generally a sound one to preclude reimbursement for commissions, rebates, excessive rentals, and so forth. It would be our suggestion that, if possible, the language be modified so that these amounts would be set out as excluded from payment, but that our identification and recovery of these amounts would not be mandated. It would be very difficult to do this on every single charge.

Mr. ROSTENKOWSKI. You know, Mr. Derzon, about the commitments that this administration has made with respect to eliminating the red-tape in Government. I note in this connection that the Senate bill and the House bill differ with respect to the creation of an Office of Clinical Laboratories, which goes to the issue of effective administrative coordination.

I am inclined to work with my colleagues on Interstate and Foreign Commerce with respect to this provision in their legislation. But I would like to know how many more positions you figure this bill would entail?

Mr. DERZON. This particular bill?

Mr. ROSTENKOWSKI. Yes.

Mr. DERZON. I believe it is our estimate that this bill could cost up to $3 million annually for HCFA, about $1.8 million for CDC, plus some moneys for the studies—approximately one-half of a million dollars, if I am not mistaken, was the estimate by the Congressional Budget Office for each study.

In terms of additional Federal employees, I think probably very few would be needed. The bulk of the responsibility for the management of this program would fall to States that have trained personnel to do this work. There would be some impact on CDC, because their monitoring of the labs would extend beyond interstate labs into intrastate labs, and I would have to ask the CDC about that.

Dr. LASHOF. Twenty-six people.

Mr. DERZON. Twenty-six people is their estimate.

Mr. ROSTENKOWSKI. Mr. Corman?

Mr. CORMAN. Do you keep track of what percentage of lab fees medicare pays and what percentage they reject as excessive or unwarranted?

Mr. DERZON. Right now, Mr. Corman, as you know, we pay the lowest of several factors in the determination of charges that are allowed under the medicare program. We pay the lowest of actual, customary or prevailing charges. The fact is that problems occur when we pay less than the physician charges. If the physician refuses to accept assignment the patient out-of-pocket costs are increased.

For physician services, the program is paying roughly 60 to 65 percent, and 35 percent seems to be generally the range of out-of-pocket costs. I can't give you a precise figure on the laboratories.

[Material supplied follows:]

For laboratory services the program pays about 62 percent, and the beneficiary pays about 38 percent.

Mr. CORMAN. The answer is no, right?

Mr. DERZON. That we keep track of everything?

Mr. CORMAN. If you keep track of everything.

Mr. DERZON. We keep track of a lot of things.

Mr. CORMAN. I get distressed at the medical profession and the Government. You keep moving further and further apart and become more and more proud of yourselves and the person in the middle is the alleged beneficiary, who finds that his medicare is not worth much to him.

It would be delightful if you would figure out how to compute all these low charges if it were helping the beneficiaries. But I cannot see that it does and that distresses me a bit.

Do you get into whether or not the laboratory procedure was justified?

Mr. DERZON. We are beginning to do that in some PSRO's which have begun to look at ancillary services utilization, both in the hospital and in outpatient activity. We are moving in that direction, but it is relatively limited at the present time.

Mr. CORMAN. Again, it will be a matter of your denying the beneficiary reimbursement. The doctor can still collect from the beneficiary, is that correct?

Mr. DERZON. Under the medicare program the doctor has a license to collect.

Mr. CORMAN. OK. Thank you very much.

Mr. ROSTENKOWSKI. Mr. Duncan?

Mr. DUNCAN. Thank you, Mr. Chairman.

Mr. Derzon, how are you going to accredit these laboratories? Are you still going to use the Joint Commission on Accreditation of Hospitals as in the past, or are you going a new route?

Mr. DERZON. Under the present arrangement there are multiple sets of standards for laboratory services and for the management of laboratories. This bill requires a single set of standards to be set by Government regulations. It is our belief that these standards would be higher than the present Joint Commission on Accreditation standards. We have had discussions with the Joint Commission, which, of course, has been certifying hospitals and their laboratories. It is their intention, if they can work it out, to bring their accrediting process up to the national norm.

The bill that is before you permits the Government to establish equivalencies, and they might very well be equivalencies with the Joint Commission, but everybody would have to move up to the national standards.

Mr. DUNCAN. If you don't use the Joint Commission, then you are going to use some other source which certainly would add additional costs to the medicare trust fund, is that right?

Mr. DERZON. The outside costs of this bill for HCFA are $3 million.

Mr. DUNCAN. We have found the estimates at first are small and then you triple them when you get into the program.

Mr. DERZON. I know that history well, but probably not as well as you do.

Mr. DUNCAN. Yes. Isn't that about true?

Mr. DERZON. I don't think this will be a high cost program. First of all, a number of States now have groups licensing labs, and we will be using State agencies that exist already. We will use the Joint Commission if they——

Mr. DUNCAN. Are not State programs adequate now?

Mr. DERZON. No. There are some that have standards that are apparently in excess of Federal standards, but in the main there are many States, I think 26 States, which have nothing. The balance of States have programs which are generally below the level that the CDC has set for acceptable quality standards.

Mr. DUNCAN. Isn't the standard of work of laboratories pretty good around the country?

Mr. DERZON. I would have to ask Dr. Lashof to comment on that.

Mr. DUNCAN. My question is that is it better than it was——

Dr. LASHOF. It is spotty.

Mr. DUNCAN. Spotty bad or spotty good?

[Laughter.]

Dr. LASHOF. Which is the background and which is the spots? I think there are a large number of well-equipped, modern, highly proficient laboratories that produce quality work, but there are scattered throughout the country, and varying State by State according to State standards, many laboratories whose personnel standards and procedures are not up to snuff. I think CDC has charts and——

Mr. DUNCAN. That is who you are really driving at, isn't it, the small laboratories, in some States?

Dr. LASHOF. I don't imply that every big lab is good and every small lab isn't good. Many labs in some areas are small because the demand isn't necessarily large, but they are good laboratories. Dr. LaMotte from CDC might review for you the amount of improvement they have found.

Mr. DUNCAN. If we are improving, why interrupt?

Dr. LASHOF. We are only in interstate laboratories at this point, the ones CDC has been licensing. But the current situation for medicare certification is that States will inspect laboratories for medicare. States may have different standards, and some may license laboratories and some may not.

Hospital laboratories are not inspected at all under laboratory standards per se. They are inspected as part of the hospital licensing program, which does not have any detailed specifications for the laboratory. What we are trying to do is to get a single standard for labs and not have labs separately licensed by CDC, or certified for medicare reimbursement and so forth.

Mr. DUNCAN. What States have the best licensing procedure at this time? Could you name some?

Dr. LASHOF. New York.

Mr. CORMAN. California.

Dr. LASHOF. California.

Mr. DUNCAN. What about Tennessee? [Laughter.]

Dr. LASHOF. They tell me they are working on it.

Mr. CORMAN. Spotty.

Mr. DUNCAN. Spotty good, though. [Laughter.]

Thank you.

Mr. ROSTENKOWSKI. Mr. Gradison?

Mr. GRADISON. Thank you. I notice there is a 2-year exemption to highly specialized laboratories. I have received objections to that exemption.

What is the view of your Department?

Mr. DERZON. The view of the Department is that the bill is sound, as constructed. What it says is that specialized services will be examined over the next couple of years to see if they should be brought in under the framework of this bill.

The problem is that there are multiple jurisdictions interested in a variety of kinds of laboratory work. I think I told you once before I was a hospital administrator. There are discussions and debates going on within hospitals, particularly ones that provide a broad array of services, about who should manage what laboratory services, and whether or not one license should cover everything that faintly resembles laboratory services as well as those things that are clearly laboratory services.

One such specialized service is cardiac catheterization. This activity is generally the responsibility of a cardiologist, and he usually does, or supervises, his own laboratory tests, such as blood gas work and other similar activities in a cath lab. He does so because they are parts of a larger set of essential procedures in this hospital unit.

I think this bill is fairly strong in encompassing a large part of laboratory work. In my view, the bill is a sensible approach to some of the controversial services that might be considered in the fringe of laboratory services.

Mr. GRADISON. I am not understanding what you are saying. This is a 2-year exemption, is it not?

Mr. DERZON. As I understand the bill as amended by the Commerce Committee, there is a 2-year study, but it does not bring in the labs at the end of the 2-year period. I could be wrong about that, but that is my understanding of it.

Mr. GRADISON. I want to be sure about that. They do come in on a mandatory basis. What is the point of leaving them out at the beginning if you are going to bring them in at the end of 2 years anyway? If we are sure enough to say they should be brought in in 2 years, why give them different treatment at the outset?

Mr. DERZON. These are not conventionally organized like other laboratory services are. We would have to decide who in these laboratories could supervise work, what the requirements of the technicians and technologists are, and whether the patterns around the country are different.

Mr. GRADISON. Don't you have situations where laboratories that perform these specialized services also perform less complicated services as well? I understand there are such cases, and a concern that has been expressed to me is that an exemption of laboratories that perform the specialized tests may encourage more specialized laboratories to get into other things, because they are not going to be subject to the same requirements as their competition, and therefore, you are affecting a competitive situation.

Mr. DERZON. If they are drawn up properly, the regulations would preclude a specialized lab from diversifying into conventional lab services.

Mr. GRADISON. Aren't some of those provided today by laboratories performing highly specialized services?

Mr. DERZON. Not in my experience. Most of the highly specialized labs stick with their specialities and don't go into other activities.

Mr. GRADISON. Are you saying there are none?

Mr. DERZON. I am not saying there are none. I am saying the vast bulk of the laboratories have a discrete list of activities, and they are not apt to add multiple laboratory services.

Mr. GRADISON. Now, I want to ask you about one that is providing specialized services, and some other services, as well, possibly as a convenience to the hospital or the physicians whom they serve who want to get everything done at one spot.

What would be the provisions during the first 2 years? Would those laboratories that provide these highly specialized services be totally exempt for the first 2 years, or will only those activities that relate to the specialized type of research be exempt?

Mr. DERZON. First of all, these would not be specialized research laboratories necessarily. They could be specialized clinical service laboratories.

Mr. GRADISON. That is what I meant to say.

Mr. DERZON. I intended that our regulations would cover those activities that do not represent an integral part of the specialized laboratory work. In other words, this bill provides for regulations that would cover a broad swath of conventional, routine laboratory services. As I read the bill, specialized hospital laboratories engaged exclusively in the assessment of cardiac or pulmonary function are excluded from the national standards for 2 years.

Mr. GRADISON. OK. Then if you have an institution which is not exclusively carrying out that activity, but is carrying out that activity with other clinical laboratories such as a hospital, are they subject to regulations and inspection for all their activities including those specialized activities which would not be subject to such Federal overview if they were carried out by a specialized institution that provided no other services?

Mr. DERZON. It's hard for us to define that question in sharp detail since we haven't started writing these regulations yet. But it would seem to me that in reading this bill, that if they are engaged exclusively in the assessment of cardiac or pulmonary function, they would be exempted. If they are not so engaged exclusively, they would not be exempted, and they would be subject to regulations covering their activities.

Mr. GRADISON. Let me say that I won't pursue this, except that I don't understand how the public interest is served by saying that institution "A" is exempt for 2 years, and if the same service is provided by a hospital which does other things, they are going to be totally inspected.

It seems to me not to be fair from a competitive point of view.

Dr. EMMOTT. One thing that should be noted is that laboratory standards will not be in effect in the hospitals for 3 years after enactment. The effect of the exemption would be negligible, therefore, because of the delayed effective date for standards in the hospitals.

Mr. DERZON. I would like to say, also, Mr. Gradison, that we are not talking about excluding one institution and including another. These are fragmented activities within large- or medium-sized institutions, and though they are important fragments, their principal activity isn't doing conventional laboratory specimen work. That is not what a cardiac catheterization lab does. It does take measurements, does measure blood gases and blood content, and so forth; but it is part of a much larger activity.

Mr. GRADISON. Has CDC found any evidence in this particular area of specialized services that there are no problems as far as the quality of the tests is concerned?

The kind of a better quality than the other things that you are aiming at, sir, that would justify a 2-year exemption? What do you find in the field?

Dr. LASHOF. They have no real experience with these, because these are the highly specialized services, usually in major hospitals. CDC has not been inspecting these kinds of laboratories in major hospitals.

So that we really don't have data on it. I would just comment on two points. One, to reiterate the point that the bill was trying to bring into a uniform act, hospital laboratories which have not been licensed previously. For this reason, the bill provides for a 3-year period before the standards for hospitals are enforced.

The exemption for the specialized labs is only 2 years. So their exemption will be up before the standards have to be applied anyhow, which one can question the bill writers on.

Therefore, we don't, obviously, consider it much of a problem. We will use the 2 years to try to study and answer the kinds of questions you are asking.

Mr. GRADISON. What is the purpose of the study? I understand you have to put the standards into effect at the end of 2 years anyway.

Dr. LASHOF. It depends on the standards you put into effect. The standards are relatively clear-cut for the usual laboratory. In the cardiac cath lab, there were specialized technicians who were in with the cardiologist. That was all the lab did, and it was support for the cardiologist.

Obviously, the director of laboratory pathology and the laboratory director, and so forth, would not be very appropriate for a very highly specialized function like that.

We wanted to determine what is that specialty. There may be others. We would like to use the 2 years to determine just what does fall into this classification, how these laboratories are run, what kind of people are supervising, and what kind of people they are using.

Then we will try to fit that into overall standards. I think within this period we will be very rigid about these labs being exclusively for cardiac-pulmonary functions. If they get into doing other procedures, or even those procedures for other patients, for example, if the cardiac cath lab did blood gas studies for all patients in the hospital, I am not sure I would consider that exclusively in the assessment of cardiac or pulmonary function. It has to be for the assessment of this purpose, and I don't think we would interpret their being able to branch out and do laboratory procedures routinely, or even the same procedure routinely.

Mr. GRADISON. The bill seems to say 210 days after the enactment, you have to promulgate the national standards. Well, promulgate them within a year, but 210 days, you would have to publish them. You said a 2-year period, and 3-year periods.

Dr. EMMOTT. Applications of standards to hospitals are delayed for 2 years, to allow the hospitals to come up to what we assume will be higher standards. So there is a delayed effective date for the hospitals.

Mr. GRADISON. At what point will the institutions know the rules of the game? At the end of 210 days, they will be published, 1 year after enactment, and 1 additional year beyond that, for specialized labs, and 2 additional years for the hospitals.

Dr. EMMOTT. The standards will not apply to hospital settings for 2 years after promulgation of the standards, which will be 3 years after enactment. That is one of the reasons we do not see this amendment, that was made by the Commerce Committee, as a great concern.

All it does is to allow us, as Dr. Lashof says, to look at appropriate standards for these very different kinds of laboratories. Even after the study, if we determine there will be a set of standards applying to these laboratories, they would not be applied to a hospital setting until they are applied generally to hospitals, which will be 3 years after enactment.

Mr. GRADISON. Then for everybody there is a 1-year exemption?

Dr. EMMOTT. Yes; because there are no standards.

Mr. GRADISON. For the specialized, they get 1 year and the hospitals get 2 years.

Dr. EMMOTT. As long as they are in hospitals, the effective date would be 3 years after enactment.

Mr. GRADISON. I am sorry to take so much time, Mr. Chairman. In the bottom line, you are putting different standards for competing

institutions, and I don't see the fairness of that. That is really what it comes to, and that is why I am asking all these questions. I appreciate the patience of the chairman.

Mr. DERZON. Mr. Gradison, I don't think this results in different standards for different institutions. It results in a slightly different timetable, and a different approach.

There are many things called laboratories. There are differences between laboratories that deal with specimens on a high- or medium-volume basis, and those that bring patients into a specialized setting for either a diagnostic or treatment service. The bill doesn't elaborate, but it makes that distinction, and, in effect says to the Department, "take a little more time on the specialized labs to see what kind of rules and regs you want to put together."

Mr. GRADISON. Thank you.

Thank you, Mr. Chairman.

Mr. ROSTENKOWSKI. Are there further questions?

Thank you, Doctor.

Dr. Powell and Mr. Halper. Welcome to the committee. Gentlemen, identify yourselves and your associates, and proceed with your testimony.

STATEMENT OF DR. JAMES POWELL, CHAIRMAN, LEGISLATIVE AND REGULATORY COMMITTEE, AMERICAN CLINICAL LABORATORY ASSOCIATION, ACCOMPANIED BY H. ROBERT HALPER, GENERAL COUNSEL

Dr. POWELL. Thank you. My name is James Powell. I appear here today representing the American Clinical Laboratory Association, an organization of medicare certified independent laboratories. Accompanying me today is H. Robert Halper, ACLA's general counsel. ACLA supports H.R. 10909, and urges its enactment. I want to summarize by this oral statement a longer written statement, including a variety of technical suggestions which ACLA believes will make a good bill even better.

While I am here in my official capacity as chairman of ACLA's Legislative and Regulatory Committee, happily the views I will express are mine, as well as ACLA's. So that you understand how I have arrived at these views, let me tell you that I am a pathologist and president of an independent laboratory chain operating in the southeastern part of the country, Biomedical Laboratories. I have worked with other independent laboratories and hospital laboratories. I have seen the caliber of testing conducted in some physicians' office laboratories. I have dealt with the medicare and medicaid programs for many years. As a result of this experience, shared by all other ACLA members, I feel uniquely qualified to tell you two things.

First, this subcommittee should not tolerate the payment of medicare or medicaid reimbursement to unregulated laboratories. Second, this subcommittee should not tolerate a reimbursement system that contributes to spiraling inflation in health care costs through unnecessarily burdensome mechanisms to obtain reimbursement. These are the two points I want to make here today, and I shall address them consecutively.

First, the primary purpose of H.R. 10909 is to assure that the quality of laboratory services reaches an acceptably high level. ACLA applauds this objective and wholeheartedly supports the need for enactment of this legislation. For the first time, medicare and medicaid beneficiaries, as well as the programs, will be assured of acceptable laboratory test results, regardless of whether the test is performed by a hospital or independent laboratory. However, one glaring exception continues—medicare and medicaid patients consulting physicians practicing in groups of five or less who operate laboratories in their offices will be provided absolutely no assurance that the laboratory testing done in these offices is of acceptable quality. Nowhere in title II are such physicians' office laboratories required to comply as a condition of reimbursement for testing services, with the national standards that all agree are a necessary prerequisite to quality testing performance. ACLA cannot understand why the federally financed health insurance programs would reimburse for services performed in unregulated laboratories that have been found time and time again to be deficient. Appendix I to ACLA's written statement provides evidence sufficient to make the case that the performance of many physicians' office laboratories is substandard. As a physician and a taxpayer, I object to this practice.

To cite an example, we have received a letter from a medical technologist working in a hospital, which provides dramatic testimony as to the consequences of testing performed in unregulated physicians' office laboratories. Had the author of the letter not been a knowledgeable laboratorian, her mother's condition, later diagnosed as polycythemia vera, an increase in the total red cell mass of the body, would have worsened as the physicians' office laboratory's results were erroneous, and she might have suffered from unnecessary clots and hemorrhages.

This letter, which we have provided to the committee, also demonstrates that erroneous testing can increase medical bills substantially. Thus, the medicare and medicaid programs are doubly overcharged for inferior testing. The programs pay for erroneous test results and then they pick up the added costs in treatment resulting from the erroneous test results. Thus, physicians' office laboratories seeking to provide testing services to medicare and medicaid beneficiaries should be required to comply with the national standards—even if these are separately drafted standards to reflect the less complicated activities of physicians' office laboratories—just as independent and hospital laboratories must. This recommendation stems from ACLA's concerns about both quality assurance and cost containment.

Whatever arguments may be raised as to the impracticality of subjecting physicians' laboratory testing to any controls at all, impracticality relates only to the enforcement of such regulation and not the logic of imposing such health protecting and money-saving standards.

In addition, ACLA firmly believes that there is no impediment to regulating group practices of three or more physicians, which is the definition of group practice utilized by the AMA, the AGPA, and the MGMA. ACLA fails to see the logic in the CLIA 1978's exemption of groups of five or fewer in light of this prevailing standard for

refining group practices. If a group practice of three physicians can afford to hire a manager, it should be expected to comply with the national standards.

My second point today also relates to the potential for cost containment in the medicare and medicaid programs. ACLA believes that through a few simple changes in the mechanics of reimbursement, the costs of administering the medicare and medicaid programs could be reduced.

No. 1, the Social Security Act should recognize that the provision of laboratory testing services comprises several components, including specimen collection, testing, and test result analysis. ACLA believes that the act should be amended to recognize each of these components, reimburse only the entity providing the service component, and subject each component to a reasonable charge determination. Adoption of this proposal would save the program money as follows. The medicare program currently does not recognize a specimen collection fee for independent laboratories. When ACLA recommended that the program recognize such fees, medicare officials responded that independent laboratories were expected to build the cost of collection into their pricing structure, thus establishing prices that include collection even if the laboratory does not always provide the collection service.

As a result the medicare program may be paying an independent laboratory for a service it has not performed. This problem could be eliminated if the statute authorized establishment of reasonable charges for collection services. Another example—physicians have been able to tack on to their professional component any charge they elect for analysis of test results. If the program were to recognize the existence of a service labeled test result analysis, charges for this service would be limited by the reasonable charge rules.

No. 2, each carrier should be required to compute only one prevailing charge for all part B laboratory services provided in the locality. At present, some carriers differentiate between physicians' office laboratories and independent laboratories, resulting in the calculation of two, rather than one, prevailing charges. As physicians' office laboratories tend to charge more than independent laboratories, the program could save money if the calculation of prevailing charges for services provided by the physician's office laboratories were included in the calculation of prevailing charges for services provided by independent laboratories.

No. 3, medicare and medicaid should adopt uniform claims forms and procedure codes. Adoption of this proposal will save money for both the programs and the participating laboratories as the preparation and processing of claims will be made considerably simpler. In addition, it is obvious that if participating laboratories incur fewer expenses, the resulting savings will be passed on to the program as reasonable charges are redetermined.

No. 4, this committee should authorize participating laboratories to waive payment of coinsurance amounts where collection of this payment is more costly than the money that would be received. ACLA seeks this amendment as certain carriers are presently lowering reasonable charges where payment by patients of the coinsurance amount is not required by the laboratory, despite an opinion from the medicare bureau that such lowering of reasonable charges should not occur. Inclu-

sion of this authority would save the programs money as laboratories would no longer have to raise prices to cover a reduction in reasonable charge determinations brought about by the laboratories' election not to bill the coinsurance amount because such billing is too costly.

No. 5, the committee should clarify that only the treating physician should be required to complete the diagnostic question on the claim for reimbursement of laboratory services. Laboratories cannot provide this information as they do not know it. To require laboratories to provide it adds to the cost of providing the service and accordingly results in higher prices. Again, adopting this proposal would result in savings to the programs.

ACLA firmly believes that implementation of these five recommendations would save money for both the medicare and medicaid programs. Language to accomplish these recommendations is included in our written statement, which, by the way, includes some other suggestions that, due to time constraints, I have not been able to explain today.

I do hope that these other recommendations, such as, amendments of the employee protection clause to assure that it is not used as a shield for incompetent employees; authorization to PER States to regulate out-of-State laboratories doing 25 percent rather than 10 percent of their business in that PER State; and modification of the provision requiring automatic licensure revocation of a laboratory if one of its employees is convicted of violating CLIA or the Social Security Act, even if such conduct is unauthorized by the laboratory—will also be given favorable consideration.

If I could leave one principal message with you today it would be that with slight adjustments to the Social Security Act, savings can be had. With inclusion of physicians' office laboratories in the regulatory scheme envisioned for laboratories receiving medicare or medicaid reimbursement, additional savings can be achieved, and the health of medicare and medicaid beneficiaries can be protected.

We should assure that medicare and medicaid patients receive acceptable testing services, regardless of where they are performed. Thank you.

[The prepared statement follows:]

STATEMENT OF THE AMERICAN CLINICAL LABORATORY ASSOCIATION

The American Clinical Laboratory Association (ACLA), an organization of large and small federally regulated independent clinical laboratories that provide services to patients in every state in the country, is pleased to submit this statement in support of H.R. 10909. ACLA believes that CLIA '78 is badly needed and urges this Subcommittee to report the bill favorably. However, ACLA does have a few recommendations, which if adopted, would improve Title II of the bill which proposes to amend the Social Security Act. ACLA members feel qualified to comment on Title II as each is certified pursuant to the Medicare Conditions for Coverage of Services of Independent Laboratories and has dealt with the Medicare program for a number of years. Additionally, nearly all ACLA members participate in the Medicaid program.

Summarized, ACLA's recommendations with regard to Title II include the following:

(1) A requirement that all physicians receiving reimbursement pursuant to the Medicare or Medicaid programs for laboratory services performed in their offices obtain Medicare certification for such office, based upon compliance with the national standards established pursuant to Section 371 of the Public Health Service Act (as proposed by § 101 of H.R. 10909):

(2) Consideration be given to adopting a rule that the only entity to which reimbursement for laboratory services will be made is the entity performing the testing service;

(3) A requirement that one prevailing charge screen be developed for all Part B laboratory services provided within a locality;

(4) A requirement that the Medicare and Medicaid programs recognize a fee for collection of specimens and that that collection fee be paid to the entity providing the service;

(5) Elimination of proposed Section 1132 suggesting a ban on percentage rental or lease arrangements as such ban is impractical and would impose an untenable burden on the carriers;

(6) A requirement that the Medicare and Medicaid programs develop and utilize uniform claims forms and procedure codes;

(7) Authorization for waiver of co-insurance payments where collection would be more costly than the amount collected;

(8) Clarification that only the physician is required to provide diagnosis information on claims forms;

(9) Adoption of certain technical amendments.

A discussion of these recommendations, as well as certain technical points follows, together with proposed amendatory language with which these recommendations could be incorporated into H.R. 10909.

PHYSICIANS' OFFICE LABORATORIES RECEIVING REIMBURSEMENT PURSUANT TO TITLES XVIII OR XIX SHOULD BE CERTIFIED AS IN COMPLIANCE WITH THE NATIONAL STANDARDS

ACLA believes that when Federal dollars are being used to reimburse, in whole or in part, the provision of laboratory testing services, the federal government has both the right and the obligation to insure that these dollars are being spent for high quality services. Presently laboratory testing performed in physicians' offices is exempt from federal quality assurance controls even if reimbursement for such services is being made by the Medicare or Medicaid programs. ACLA strongly urges this Committee to amend Title II of H.R. 10909 to require that physicians who receive Medicare or Medicaid reimbursement for testing services provided in laboratories they operate obtain Medicare certification, just as independent and hospital laboratories must. Such Medicare certification should be based upon compliance with the national standards, as mandated by proposed § 371(a) of the Public Health Service Act. ACLA makes this recommendation because testing in physicians' office laboratories is frequently unreliable, as demonstrated in the attached statement entitled "Laboratory Testing in Physicians' Offices". The following amendment to proposed § 1861(s) would assure that federal monies are not spent on unreliable testing.

Strike out the period following the word "Act", insert in lieu thereof a semicolon and insert the following phrase after the word "Act" at page 70 of the Commerce Committee Report on H.R. 10909 and at line 17 of page 42 of the February 9, 1978 print of H.R. 10909: "no diagnostic test performed in any laboratory located in the office of, or supervised by, a licensed physician, dentist, or podiatrist, shall be included in paragraph (3) unless such laboratory meets the national or PER state standards established under Part H of Title III of the Public Health Service Act."

If this amendment were adopted, the second sentence of § 1861(s) of the Social Security Act would read as follows: "No diagnostic test performed in any laboratory shall be included in paragraph (3) unless such laboratory meets applicable Federal or State licensing requirements under Part H of Title III of the Public Health Service Act; *no diagnostic test performed in any laboratory located in the office of, or supervised by, a licensed physician, dentist or podiatrist, shall be included in paragraph (3) unless such laboratory meets the national or PER state standards established under Part H of Title III of the Public Health Service Act.*"

If this Subcommittee determines that it cannot require physicians' office laboratories receiving federal reimbursement funds to comply with the national standards, ACLA would suggest a compromise pursuant to which Section 1861(s) would require that laboratories operated by group practices of three or more physicians comply with the national standards. ACLA recognizes that Title I of H.R. 10909, § 372(c)(3)(B), would exempt group practice laboratories operated by as many as five physicians. We believe that group practices that large

should not be exempt from the national standards, under any circumstances, for the following reasons: (1) the volume of tests performed is sufficiently large to warrant imposition of quality assurance standards; (2) the profession itself, as articulated by the American Medical Association, the American Group Practice Association and the Medical Group Managers Association, defines group practices to be those physician arrangements consisting of three or more physicians; (3) many group practices of three or more physicians employ managers; and (4) if these group practices have sufficient business to require and income to afford the services of a manager, they should comply with quality assurance standards. These arguments apply with even greater force where the federal government is helping to pay for the services provided in such a laboratory.

The following amendment to proposed § 1861(s) would assure that federal monies are not spent on unreliable testing performed by group practices of three or more physicians:

Strike out the period following the word "Act", insert in lieu thereof a semicolon and insert the following phrase after the word "Act" at page 70 of the Commerce Committee Report on H.R. 10909 and at line 17 of page 42 of the February 9, 1978 print of H.R. 10909: "no diagnostic test performed in any laboratory located in the office of, or supervised by, a group practice of three or more licensed physicians, dentists, or podiatrists, shall be included in paragraph (3) unless such laboratory meets the national or PER state standards established under Part H of Title III of the Public Health Service Act."

If this amendment were adopted, the second sentence of § 1861(s) of the Social Security Act would read as follows: "No diagnostic test performed in any laboratory shall be included in paragraph (3) unless such laboratory meets applicable federal or State licensing requirements under Part H of Title III of the Public Health Services Act; *no diagnostic test performed in any laboratory located in the office of, or supervised by, a group practice of three or more licensed physicians, dentists or podiatrists, shall be included in paragraph (3) unless such laboratory meets the national or PER state standards established by Part H of Title III of the Public Health Service Act.*"

In addition to the obvious health benefits that would be achieved through adoption of either of these amendments, ACLA believes that the Programs would save money as they would not pay for useless, erroneous test results, and they would not pick up the added costs of treatment stemming from erroneous testing.

AMENDMENTS THAT WOULD RESULT IN COST SAVINGS TO THE PROGRAM

ACLA believes that both the Medicare and Medicaid Programs could save money through certain amendments to the Social Security Act. A discussion of each of these proposals follows.

H.R. 10909 presently proposes a truth in billing approach to Medicare/Medicaid reimbursement, pursuant to which physicians seeking reimbursement for testing services would be required to disclose on the claim form the name of the laboratory performing the testing and the price he paid for such tests if he purchased them from a laboratory other than his own. His reimbursement would then be limited by the reasonable charge rules. While ACLA feels that this proposal is an improvement over the current situation, ACLA, on balance, believes that a direct program billing approach would be preferable to the truth in billing proposal. Under such a direct program billing approach only the entity performing the service would be eligible to receive reimbursement from the programs. In the case of Medicare, such reimbursement would occur pursuant to an assignment from the beneficiary. ACLA supports this approach as it ends opportunities for abuse and would eliminate physician markup.

Hand in hand with this proposal, however, must come a recognition that laboratory services are comprised of several components, including specimen collection, testing and physician analysis of the test results. ACLA believes that each entity providing each of these services should be reimbursed for them as part of this direct program billing approach to reimbursement. Thus, a collection fee of, for example, $4 per patient should be established and paid to the entity collecting the specimen, which is usually the treating physician or the testing laboratory. The testing laboratory should be reimbursed its reasonable charge and the physician should be provided a fee for analysis of the test results.

ACLA is convinced that recognition of these components would result in cost

savings to the Programs, for the following reasons. ACLA has long advocated the need for Medicare/Medicaid recognition of specimen collection fees, subject to reasonable charge limitations. When ACLA has made this proposal to Medicare officials, they have responded that the statute prohibits such reimbursement, as collection is not a medically necessary service. Instead, Medicare officials indicated that they expected laboratories to build the cost of collection into their pricing structures. This policy means that laboratories may set prices that include collection even if the laboratory does not always provide the collection service. In addition, it means that collection is built into the price of every test even if only one specimen is necessary for the performance of several tests. Thus, the Medicare program may be paying an independent laboratory for a service it has not performed, or it may be paying the laboratory more than once for the same service. Because Medicare officials feel that the Social Security Act prohibits recognition of collection fees, ACLA strongly urges this Committee to provide the Program with the necessary authority. ACLA is convinced that the Program would save money if it paid a per patient specimen collection fee, subject to reasonable charge rules, to the entity providing the service.

In the same vein, ACLA believes that physicians are entitled to a fee for analyzing the laboratory test results. However, this fee should also be subject to reasonable charge limitations.

Another cost savings device in ACLA's direct program billing proposal is the suggestion that carriers should calculate only one prevailing charge for Part B reimbursable laboratory services in the locality. Such a requirement would end the all too frequent practice of carriers to establish separate prevailing charges for each class of laboratory—independent, physicians' office and hospital out-patient. An end to this practice is desirable as each of these classes of laboratories has a tendency to charge widely varying fees for the same service. Thus, physicians tend to set prices for services performed in their office laboratories that are markedly higher than the prices set by independent laboratories, and the prevailing charges for services provided in physicians' office laboratories are accordingly higher than prevailing charges for the same services provided by independent laboratories. To assure that the Program does not reimburse physicians at higher levels than the levels received by laboratories for the same testing services, carriers should be required to establish one prevailing charge for all Part B laboratory services, rather than separate prevailing charges for independent and for physicians' office laboratories.

Further cost savings could be obtained if Medicare and Medicaid used uniform claims forms and procedure codes. Adoption of such a proposal will save money for both the programs and participating laboratories as the preparation and processing of claims would be made considerably simpler. In addition, it is obvious that if participating laboratories incur fewer expenses, the resulting savings will be passed on to the program as reasonable charges are redetermined.

ACLA also believes savings could be achieved if the Social Security Act authorized carriers to waive payment by Medicare beneficiaries of co-insurance where the cost of collection would exceed the amount collected. ACLA seeks this amendment as certain carriers are presently lowering reasonable charges where payment of the co-insurance amount is not required by the laboratory, despite an opinion from Medicare that such lowering of reasonable charges should not occur in such a situation. Inclusion of this authority would save the Program money as laboratories would no longer have to raise prices to cover a reduction in reasonable charge determinations brought about by the laboratories' election not to bill the co-insurance amount because such billing is too costly.

Finally, ACLA asks this Subcommittee to clarify that only the treating physician is required to complete the diagnosis question on the claim for reimbursement of laboratory services. Laboratories cannot provide this information as they do not know it. To require laboratories to provide it adds to the cost of providing the service and accordingly results in higher prices. Again, adoption of this proposal would result in savings to the Programs.

To implement these cost savings proposals, the following amendments are necessary.

1. Section 1862(a) of the Social Security Act should be amended by adding a new paragraph 14 as follows:

"SEC. 1862(a) Notwithstanding any other provisions of this title, no payment may be made under Part A or Part B for any expenses incurred for items or services—

* * * * * * *

(14) which are diagnostic laboratory services, if—

(A) the bill or written requests for payment for such services is submitted by anyone other than (i) the Medicare beneficiary for whom the tests were performed, (ii) the person who provided such services, or (iii) a person or laboratory to which a specimen was initially referred for testing, or

(B) the laboratory providing the service does not meet the requirements of section 1861(e)(9) and the second sentence of section 1861(s).

* * * * * * *

2. Section 1842 of the Social Security Act should be amended by replacing the proposed new subsection (h) with the following:

(h) The Secretary shall develop uniform procedures that all carriers shall follow in reimbursing for diagnostic laboratory services which shall include—

(1) adoption of uniform procedure codes;

(2) adoption of uniform claims forms;

(3) computation of one prevailing charge per locality for all laboratory tests reimbursed on a reasonable charge basis;

(4) adoption of a fee for specimen collection and test analysis in addition to reasonable charges for test performance;

(5) adoption of a requirement that the person ordering the test provide information concerning diagnosis;

(6) authority to waive co-insurance payments as required by § 1833 (a) of this Title where the cost of collecting such co-insurance would exceed the amount collected;

Title XIX of the Social Security Act should be amended to reflect these changes as follows:

Section 1902(a) of the Social Security Act should be amended (A) by striking out "and" at the end of paragraph (39); (B) by striking out the period at the end of paragraph (40) and inserting in lieu thereof "and" and (C) by adding after paragraph (40) the following new paragraph:

"(41) provide that reimbursement for laboratory services meets the conditions set forth at sections 1842(h) and 1862(a)(14) of the Social Security Act."

AMENDMENT OF PROPOSED SECTION 1132

Section 1132 should be deleted from H.R. 10909 as it is administratively impractical and would impose an untenable burden on carriers. The recent enactment of H.R. 3, the Medicare/Medicaid Antifraud and Abuse Amendments of 1977, should be sufficient to eliminate the problems that the drafters of the provision sought to solve. ACLA fears that if the provision is retained it will not be enforced, and it may stifle innovative cost savings arrangements for the provision of laboratory services.

If the Subcommittee is unwilling to eliminate the provision, ACLA urges that it be amended as follows.

First, to assure that hospitals are encouraged to enter into arrangements with laboratories outside of the hospital where such arrangements are advantageous for economic or service reasons, the hospital exclusion established by proposed section 1132 to the Social Security Act, should be amended as follows:

"(1) Strike the words 'which is located in' in the first parenthetical phrase appearing at pg. 64 of the Commerce Committee Report on H.R. 10909 and at lines 15–16 of pg. 39 of the February 9, 1978 print of H.R. 10909.

"(2) Strike the phrase 'and which provides services primarily in connection with the furnishing by the hospital of other inpatient or outpatient services)' in the first parenthetical phrase appearing at pg. 64 of the Commerce Committee Report on H.R. 10909 and at lines 15 through 17 of page 39 of the February 9, 1978 print of H.R. 10909.

"(3) Add the word 'to' after the words 'clinical laboratory' appearing in the first parenthetical phrase on page 64 of the Commerce Committee Report on H.R. 10909 and at line 14 of page 39 of the February 9, 1978 print of H.R. 10909."

If these changes are adopted the parenthetical appearing on page 64 of the Commerce Committee Report on H.R. 10909 and at line 13 of page 39 of the February 9, 1978 print of H.R. 10909 would read: "(other than such a service which is provided by a clinical laboratory to a hospital)."

This amendment will guarantee the necessary flexibility to enable hospitals and outside laboratories to enter into cost savings arrangements even if such arrangements utilize percentage payments.

Second, proposed Section 1132(2) of the Social Security Act would prohibit reimbursement for any amount payable to any facility under any rental or lease arrangement where such amount is unrelated or disproportionate to the market value of this facility or is directly or indirectly determined wholly or in part as a per centum, fraction, or portion of the charge or cost attributed to laboratory service. ACLA recognizes that the inclusion of this section is intended to end abusive rental arrangements under which physicians lease space to a laboratory and receive in return unreasonably high payments. Nonetheless, this language could create a problem by flatly prohibiting all percentage arrangements, regardless of how reasonable they might be.

ACLA suggests that H.R. 10909 be amended to ban percentage arrangements only when they result in excessive payments. To accomplish this change, two options are available. First, the bill could be amended by adding after the word "service" at § 1132(2)(B) appearing on page 64 of the Commerce Committee Report and at line 7 of page 40 of the February 9, 1978 print the phrase "and is excessive of the usual and customary charge for such rental or lease arrangement." Thus, the provision would read:

"(2)(B) is, directly or indirectly, determined, wholly or in part, as a per centum, fraction, or portion of the charge or cost attributed to the laboratory service *and is excessive of the usual and customary charge for such rental or lease arrangement.*"

The second option would be to add after the word "service" at § 1132(2)(B) appearing on page 64 of the Commerce Committee Report and at line 7 of page 40 of the February 9, 1978 print the following phrase: "unless such charge or cost is found not to be excessive for such rental or lease arrangement." Adding this language would make the provision read:

"(2)(B) is, directly or indirectly, determined, wholly or in part, as a per centum, fraction, or portion of the charge or cost attributed to the laboratory service *unless such charge or cost is found not to be excessive for such rental or lease arrangement.*"

ACLA also seeks an amendment to authorize that the provisions of new section 1132 of the Social Security Act will become effective 12 months following enactment of the legislation in order to allow laboratories time to renegotiate existing contracts. We suggest that this amendment should be added at the end of § 1132 on page 64 of the Commerce Committee Report and at line 8 of page 40 of the February 9, 1978 print of H.R. 10909. The amendment should read: "The provisions of this subsection shall become effective 12 months from the date of enactment."

TECHNICAL AMENDMENTS TO TITLE II

ACLA suggests that proposed Section 1902(a)(30) of the Social Security Act should be amended by adding the phrase "for comparable services by the provider of such services" at page 73 of the Commerce Committee Report and at line 20 of page 48 of the February 9, 1978 print of H.R. 10909 after the parenthetical phrase "(determined without regard to administrative costs which are related solely to the method of reimbursement for such services)" and before the words "to any person or entity". We recommend this clarifying amendment because a laboratory may perform identical tests and at the same time provide varying levels of service that justify different prices for these tests. For example, a laboratory provides a different service when it draws a specimen for analysis than it does when the physician ordering the test draws a specimen. The laboratory ought to be able to charge different prices for identical tests when the drawing services it provides are not comparable, without experiencing disallowance of its claims under section 1902(a)(30).

We believe that the amendatory language we have proposed takes cognizance of the fact that laboratory tests and services differ. In addition, adding this language would make this provision parallel to proposed section 1902(a)(23) which includes the comparability language and which recognizes the fact that services vary as do the prices for such services. (See page 73 of the Commerce Committee Report and lines 16–21 of page 47 of the February 9, 1978 print of H.R. 10909.) If this amendment were adopted, the new portion of section 1902(a)(30) would read as follows: "and, in case of laboratory services referred to in section 1905(a)(3), such payments do not exceed the lowest amount charged (determined without regard to administrative costs which are related solely to the method of reimbursement for such services) *for comparable services by the provider of such services* to any person or entity for such services by that provider of laboratory services."

We also feel that the parenthetical phrase "(determined without regard to administrative costs which are related solely to the method of reimbursement for such services)" which appears both at section 1902(a)(30) and section 1902(a)(23) should be redrafted as it is ambiguous and it appears to conflict with subsection 373(c)(2)(C) (see page 56 of the Commerce Committee Report and in particular lines 18–24 on page 16 of the February 9, 1978 print of H.R. 10909). ACLA suggests that amendment of the parenthetical phrase (at line 16 of page 47 and line 20 of page 48 of the February 9, 1978 print and page 73 of the Commerce Committee Report) would clarify the intent of the parenthetical phrase. ACLA recommends that the parenthetical be amended to read as follows: "(determined without regard to administrative costs for which reimbursement will be made provided they are related solely to the method of reimbursement)."

OTHER AREAS OF THE BILL IN NEED OF AMENDMENT

While ACLA is pleased to have the opportunity to reconfirm its support of H.R. 10909, and although we have confined the bulk of our comments to Title II, we do believe that certain provisions of Title I should be amended as well. Summarized, ACLA suggests the following:

1. Exempt physicians' office laboratories should be subject to minimal, specifically designed quality assurance standards.
2. PER states should only be authorized to regulate, upon approval by the Secretary, those out-of-state laboratories doing at least 25% of their business in that PER state. Adoption of this suggestion would minimize regulatory overlap and duplication and would cut down enforcement costs.
3. Non PER states should not be allowed to regulate personnel located outside of their borders.
4. Standards separate from those applicable to testing laboratories should be developed for collection stations since the functions of the two types of facilities are entirely different.
5. The employee protection clause should be amended so that it protects both employees and employers, assuring that the provision cannot be used as a shield by an incompetent employee. Addition of the word "solely" between the words "employment" and "because" at proposed § 376(c)(1) of the Public Health Service Act, appearing on page 60 of the Commerce Committee Report on H.R. 10909 and at line 24 of page 26 of the February 9, 1978 print of H.R. 10909 would guard against use of this provision as a shield.
6. Research laboratories that charge for the tests or procedures that they perform should comply with the national standards and obtain the necessary licenses.
7. The requirement that an Office of Clinical Laboratories and an Advisory Council be established should be reinstated.
8. A rural interstate laboratory that is currently licensed for interstate business should not be eligible for the rural personnel waiver, as such laboratory currently meets the interstate personnel standards.
9. If a person is convicted of violating CLIA or the Social Security Act, the license of the laboratory with which he was connected should not be automatically revoked unless the convicted person had an ownership interest of 5 percent or more in the laboratory.
10. The standard for injunctive relief should be changed from "significant hazard" to "substantial risk to the public health".

ACLA would be pleased to submit additional testimony on these ten points if the Subcommittee wishes it.

LABORATORY TESTING IN PHYSICIANS OFFICES

The American Clinical Laboratory Association (ACLA), consisting of federally regulated independent laboratories, submits this statement in support of its position that Title II of the Clinical Laboratory Improvement Act of 1978, presently pending before the Ways and Means Committee of the House of Representatives as H.R. 10909, should be amended to require that physicians' office laboratories receiving reimbursement under the Medicare or Medicaid programs be certified by the Secretary of Health, Education and Welfare as in compliance with the national or PER state standards, established pursuant to §101(a) of H.R. 10909. ACLA's position reflects its belief that the quality of laboratory testing performed in physicians' office laboratories is substandard, that the volume of such testing is sufficiently high to warrant federally imposed safeguards to improve the caliber of such testing, and that federal monies should not be spent on substandard services.

ACLA is aware that the Department of Health, Education and Welfare believes that the absence of data about both the quality and volume of such testing makes it difficult to forge a responsible program for such laboratories, while ACLA contends that the data presently available supports the needs for greater control over the operations of physicians' office laboratories where such offices receive federally funded reimbursement.

THE QUALITY OF LABORATORY TESTING IN PHYSICIANS' OFFICE LABORATORIES IS SUBSTANDARD

Perhaps the most comprehensive study of laboratory performance, comparing various types of laboratories,[1] is A Proficiency Test Assessment of Clinical Laboratory Capability in the United States, undertaken by the Technical Analysis Division of the National Bureau of Standards and prepared for the Department of Health, Education and Welfare.[2]

The major objective of the study was to obtain measures of capability for several different types or groups of clinical laboratories and to determine if there are basic differences in analytical accuracy among these groups which would warrant remedial action by public agencies or the private sector.[3]

All of the laboratories participating in the survey did so voluntarily. Thus, it is reasonable to assume that their performance represents the highest level that laboratories obtain, as: (1) laboratories fearing they would not perform well would not have agreed to participate; and (2) participating laboratories probably gave special attention to the proficiency test sample. Nonetheless the results are disturbing. The survey tested performance in clinical chemistry, hematology and microbiology. Of the five types of laboratories participating, physicians' offices were the least precise in hematology, and the second least precise in clinical chemistry and microbiology.[4] For example in the area of microbiology, physicians' offices misidentified 20.8% of the samples—one in five,[5] performing more poorly than each of the other types of laboratories except Medicare hospital laboratories.[6] The survey concludes that "[t]he data indicate that high volume laboratories may be more proficient than smaller laboratories, such as those which serve Doctor's Offices and Medicare Certified Hospitals."[7]

In response to these results the report makes the following recommendations: "(a) Satisfactory performance in a microbiology proficiency testing program conducted under the auspices of either federal or other approved authorities should be a legislative requirement for all clinical laboratories analyzing microbiological specimens, regardless of their inter- or intrastate status * * *"[8]

The report also suggests that HEW request additional authority as follows: (a) The licensing authority of the Clinical Laboratory Improvement Act of 1967 could be extended to include those laboratories which are presently exempt but whose normal workload includes the identification of microbiological specimens. An alternate means of insuring the desired level of laboratory performance is to identify and accredit proficiency testing programs currently being operated by State or local governments or professional societies. Under this alternative, the Federal Government should maintain the authority to withhold or withdraw the license of any laboratory whose demonstrated performance in the identification of micro-biological specimens does not at least meet existing minimum standards under CLIA '67.[9]

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[1] Interstate laboratories licensed pursuant to CLIA '67; hospital laboratories accredited by the Joint Commission on Accreditation of Laboratories; Medicare certified hospital laboratories; Medicare certified independent laboratories; and physicians' office laboratories operated by members of the American Academy of Family Physicians and the American Society of Internal Medicine.

[2] NBSIR 73–163 (May 1973).

[3] *A Proficiency Test Assessment of Clinical Laboratory Capability in the United States*, NBSIR 73–163 (May 1973), p. iii.

[4] *Ibid* pgs. 85–86.

[5] *Ibid*, p. 73.

[6] *Ibid*, p. 76.

[7] *Ibid*, p. 86.

[8] *Ibid*, p. 88.

[9] *Ibid*, p. 89.

Another study, conducted by the state of Connecticut, sheds light on physicians' office laboratory performance. In 1974 Connecticut initiated an experiment, utilizing proficiency testing, to measure such performance.[10] The tests and number of participants were as follows:

	Physicians
Blood Chemistry	17
Urinalysis	23
Hemoglobin	21
Differential blood cell count	16

Blood chemistry included glucose, blood urea nitrogen, uric acid and cholesterol. Urinalysis included tests for ketones, protein, blood, pH, pregnancy and specific gravity. None of the specimens was difficult to analyze.

In analyzing the general level of performance by these physicians' office laboratories, Jesse S. Tucker, Ph.D., Assistant Director of the Laboratory Division of the State Department of Health, made the following observation.

Although the number of participants was small, those involved did so voluntarily. This is generally interpreted to mean that those who voluntarily participated were those who felt that they would perform well. *Since less than 50 percent of the physicians' office participants performed acceptably in chemistry, it must be concluded that the general level of performance by participating physicians was poor*[11] (emphasis added).

A chart, entitled Table I, comparing physicians' performance with that of registered laboratories is attached to Dr. Tucker's letter. It is extremely informative and should be consulted.

Dr. Tucker's letter is in response to a letter from Senators Kennedy and Javits seeking information about physicians' office laboratory performance. The Senators sent similar letters to the Illinois Department of Health, the California Department of Health, the Nevada Department of Health and Welfare, the Maryland Department of Health and Mental Hygiene, and the Department of Health, Education and Welfare. The replies they received are attached hereto. Although each of these letters provides varying information about the level of performance of such laboratories, they all indicate that proficiency testing plays an essential role in aiding physicians' office laboratories.

The College of American Pathologists (CAP) has for many years offered a proficiency testing program entitled PEP for physicians. In analyzing the results of participants in PEP, C.A.P. has found a clear improvement in performance, as demonstrated by the following statistics.

COMPARISON OF PERCENTAGE OF UNACCEPTABLE RESULTS OF PARTICIPANTS FROM 1949 TO 1973[1]

	1949	1969	1973
Glucose	16.3	8.0	7.3
Urea nitrogen	63.5	13.3	12.4
Chloride	16.4	5.2	2.7
Calcium	27.6	11.1	5.9
Cholesterol	33.7	18.5	8.3

[1] Statistics cited by Russel Eilers, M.D., on Oct. 14, 1975, in San Francisco, Calif.

Supporting the C.A.P. contention that participation in proficiency testing programs improves performance is the letter from HEW. It states that compliance with the proficiency testing, quality assurance and inspection standards has contributed to the improvement of performance by physicians' office laboratories, subject to the Medicare Conditions for Coverage of Services of Independent Laboratories. The letter further notes that such laboratories have experienced little difficulty in employing qualified personnel and maintaining requisite records. However, it does add that if the personnel requirements were extended to all physicians' office laboratories, difficulties might arise.

In characterizing performance, HEW states:

"As a general rule, it appears that physicians' office laboratories have more difficulty initially meeting the Medicare requirements (personnel, quality control and proficiency testing) but once compliance is reached, their performance is maintained at an acceptable level." [12]

[10] March 6, 1977 letter from the State of Connecticut to Senators Edward M. Kennedy and Jacob K. Javits.

[11] *Ibid*, p. 2.

[12] Attachment to April 20, 1977 letter from Thomas M. Tierney to Senator Edward M. Kennedy. p. 7.

This statement, by itself, capsulizes the reasons for bringing physicians' office laboratories within the scope of CLIA '77. While such offices may have more initial difficulty in meeting the standards (presumably because such laboratories have traditionally operated free of most of them), once such standards are implemented, these laboratories perform satisfactorily. Thus, the conclusion that such laboratories should be subject to quality assurance standards is inescapable.

Other experts in the area support the contention that quality assurance standards should be applied to physicians' office laboratories.

Paul Fugazzotto, Ph. D., Chief of the Nevada Bureau of Laboratories and Research has stated:

"The present [Nevada] policy is that physicians' offices are required to meet the very same quality assurance standards that are applied to all labs. The fact that they are doing test (sic) on their own patients does not excuse them from doing a slipshod job for which they will charge the patient and perhaps even make a wrong diagnostic decision." [13]

Robert I. Bosman, Deputy Director of the Maryland Laboratories Administration has made similar statements.

"I firmly believe most physicians desiring to operate laboratories for their own patients, or groups of physicians with an office laboratory should be required to meet and maintain the same standards of proficiency and quality control as any other laboratory, i.e., independent, hospital, etc., if we are going to strive for safe and reliable laboratory procedures within the state and in the nation." [14]

Richard M. Bailey, Professor of Health Economics at the University of California, Berkeley, conducted a conference to discuss laboratory economics and public policy on June 14, 1976. One of the issues discussed was uniform standards of quality. The following consensus was obtained.

"[T]here was nearly unanimous agreement that there should be uniformly high-quality standards for hospital, independent laboratories and physicians' office laboratories." [15]

Thus, ACLA believes that officials experienced with laboratory regulatory programs support the application of quality assurance standards to physicians' office laboratories.

THE VOLUME OF TESTING PERFORMED IN PHYSICIANS' OFFICE LABORATORIES JUSTIFIES COMPLIANCE WITH FEDERALLY IMPOSED STANDARDS

One of the areas concerning physicians' office laboratories that has caused considerable concern is the absence of any knowledge as to their number. While it is true that no hard and fast census exists, certain information is available. In testifying before the Subcommittee on Health and the Environment, Robert W. Chambers, M.D., a professor of clinical pathology at Georgetown University School of Medicine, estimated that in 1975 physicians' office laboratories performed twenty-five percent of total laboratory tests. and received gross revenues of $1.6 billion, as compared with the total market of $10.2 billion.[16]

On March 14, 1975, the American Society of Internal Medicine (ASIM) published its *National Survey of Physicians' Office Laboratories*, HSM 110-72-341, which it had prepared under contract with the Department of Health, Education and Welfare.

ASIM sent questionnaires to 6,400 non-pathologist physicians, representing six percent of the potential respondent universe, seeking data on these physicians who performed laboratory work in their offices.[17] It would not be difficult to calculate the results had the questionnaire been mailed to all potential respondents and thereby obtain a reasonable estimate of the number of office labs in existence.

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[13] March 28, 1977 letter from Fugazzotto to Senators Jacob K. Javits and Edward M. Kennedy, p. 3.

[14] March 10, 1977 letter to Senator Jacob Javits from Robert I. Bosman, p. 2.

[15] August 31, 1976 letter from Richard M. Bailey to Senators Jacob K. Javits, Edward M. Kennedy and Congressman Paul G. Rogers.

[16] Hearings on H.R. 11341 before the Subcommittee on Health and the Environment of the Committee on Interstate and Foreign Commerce—House of Representatives, 94th Cong., 2d Sess., p. 324.

[17] *National Survey of Physicians' Office Laboratories*, HSM 110–72–341 (March 14, 1975) pp. 4–5.

Most of the physicians responding to the survey were in sole practice.[18] Group practices maintaining office laboratories most often consisted of between two and five physicians.[19]

Of those responding to questionnaires, the following utilized some internal quality control techniques.[20]

	Percent
Family practitioners	37
Internists	62
General surgeons	40
Osteopaths	37

Participation in proficiency testing programs was as follows: [21]

	Percent
Family practitioners	10
Internists	30
General surgeons	14
Osteopaths	5

In addition to the ASIM study, certain state officials have estimated the number of such office laboratories within their jurisdiction. California officials estimate that there are between 6,000 and 8,000 office labs in that state.[22] Maryland officials estimate that "approximately 50 percent of all laboratory tests are performed by physicians' office laboratories as opposed to regulated Independent or Interstate laboratories." [23] Illinois officials indicate that 2,300 physicians have enrolled in proficiency testing programs, in response to an Illinois law requiring one-third of such labs to enroll in such programs.[24] These officials indicate that the 2,300 figure does not yet equal one-third.[25] Thus, it seems reasonable to assume that there are more than 6,900 physicians' office laboratories in Illinois.

The Department of Health, Education and Welfare states that there are 492 physicians' office laboratories regulated pursuant to the Medicare Conditions for Coverage and Services of Independent Laboratories, by virtue of their acceptance of referral work or the fact that they held themselves out as able to accept referral work.[26]

While none of these studies or observations provide the types of data that must be obtained, they do indicate that testing in physicians' offices is sufficiently pervasive so as to require mandated quality assurance standards. Thus, ACLA recommends that OMB and HEW support amendment of CLIA 1977 so as to authorize both the development of an effective regulatory program for physicians' office laboratories consisting of the recommendations ACLA has made in its memorandum entitled CLIA '77 and Physicians' Office Laboratories and the completion of a study of such laboratories to aid the Secretary in determining the most effective way to regulate them. Such amendment should allow the Secretary to change the physicians' office laboratory regulatory program to accommodate the report's recommendations.

Mr. ROSTENKOWSKI. Are there any questions, Mr. Duncan?

Mr. DUNCAN. No questions.

Mr. ROSTENKOWSKI. Mr. Gradison?

Mr. GRADISON. I notice under section 203 of the bill it will be possible under medicaid for competitive bidding to be used for a 3-year period for the provision of clinical laboratory services.

I would like to know, first of all, how you feel about this; and second, what would you think about extending the same concept to medicare, which is in our jurisdiction.

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[18] *Ibid*, p. 8.
[19] *Ibid*, p. 8. This statistic is particularly interesting as CLIA '77 would offer exemptions to group practices of five or fewer.
[20] *Ibid*, p. 15.
[21] *Ibid*, Table 16.
[22] March 10, 1977 letter from Floyd W. Hartmann, to Senators Edward M. Kennedy and Jacob K. Javits, p. 1.
[23] March 10, 1977 letter from Robert I. Bosman, to Senator Jacob Javits, p. 2.
[24] April 15, letter to Senator Jacob K. Javits and Edward M. Kennedy from Paul Q. Peterson, p. 2.
[25] *Ibid*, p. 2.
[26] April 1, 1977 letter to Senator Edward M. Kennedy from Thomas M. Tiernev, p. 1.

Mr. HALPER. Let me answer that. I think this is perhaps an idea whose time has come as long as it is proposed on an experimental basis to be tried in certain areas.

I think, too, that little is known about this. We think it probably is a good idea, but it could have dramatic ramifications that could impact unfavorably on small laboratories.

Mr. GRADISON. Unfavorably?

Mr. HALPER. Unfavorably. If tried on an experimental basis for several years, we could see from the results of these test programs how they work.

Mr. GRADISON. How about permitting the experiments to extend to medicare as well, perhaps by providing that in any given community in which the medicaid experimentation plays, some arrangement, at least, be considered for medicare applications as well.

Mr. HALPER. I think we would probably support that, but I think it would be more difficult in administering it under medicare in terms of identifying how you split up part of the medicare program.

ACLA supports this as long as the approach is confined to experimenting, and then reexamining the result to see if there are anticompetitive consequences, such as too many laboratories going out of business or other unwanted consequences because of the reduction of services. But nevertheless, it will probably result in some good cost containment.

Mr. GRADISON. Thank you, Mr. Chairman.

Mr. ROSTENKOWSKI. Thank you, gentlemen.

Dr. Hutchens, Dr. Gilbert, and Dr. Schenken. Welcome, gentlemen, if you will, identify yourselves and proceed with your statement. The committee is ready to proceed with your testimony.

STATEMENT OF DR. TYRA T. HUTCHENS, PRESIDENT, COLLEGE OF AMERICAN PATHOLOGISTS, ACCOMPANIED BY DR. ROGER GILBERT, CHAIRMAN, COUNCIL ON QUALITY ASSURANCE; AND DR. JERALD R. SCHENKEN, CHAIRMAN, COMMITTEE ON NATIONAL LEGISLATION

Dr. HUTCHENS. I am Tyra T. Hutchens, M.D., president of the College of American Pathologists. With me today are Roger K. Gilbert, M.D., and Jerald R. Schenken, M.D.

H.R. 10909 contains features which the college supports. However, it contains features which could needlessly increase the administrative burden to both Government agencies and clinical laboratories, and will unnecessarily escalate the cost of laboratory services at a time when "cost containment" is a major concern. More importantly, they may have an adverse effect on the quality of laboratory services. We have a statement for the record.

Mr. ROSTENKOWSKI. Without objection, your entire statement will be included in the record.

Dr. HUTCHENS. We would now like to offer comments and suggestions concerning specific provisions of the proposed legislation.

Mr. Chairman, the college strongly believes amendments to the Social Security Act dealing with reimbursement under Government-

financed health care programs best belong in separate legislation. Inclusion and reimbursement amendments detracts from the primary purpose of the bill, improved quality of services. However, if such amendments remain, we offer the following comments.

BILLING PROCEDURES (SEC. 202)

The college supports the concept of section 202, "Billing Procedures for Laboratory Services," which is a system commonly termed "disclosure billing." In testimony and in statements on proposed regulations to the Secretary, HEW, the college has urged that when physicians have laboratory services performed outside of their offices, the physician identify the laboratory providing the services and the amount charged to or paid by the physician, and that it be noted on the physician's bill on request for payment.

STUDY OF FINANCIAL ARRANGEMENTS (SEC. 204)

The college questions the need for the study of financial arrangements called for in section 204. The limitation of this study only to arrangements for the provision of laboratory services appears, in our opinion, discriminatory.

At the present time, the Health Care Financing Administration is considering the issuing of contracts and/or grants to non-Government organizations to carry on studies dealing with hospital-based physician reimbursement.

In our opinion, the study called for in the legislation would be duplicative of these efforts.

We would, therefore, recommend that this section be deleted from the bill.

COMPETITIVE BIDDING (SECTION 203(A) (1) AND (2))

Mr. Chairman, the college has testified on several occasions in opposition to competitive bidding as a method of providing laboratory service to patients. Our position has not changed. We foresee a serious degradation of quality in the delivery of laboratory services to medicaid beneficiaries. We strongly believe that a number of major problems would exist. A few of these are: (1) Competitive bidding ignores a primary aspect of laboratory services—quality—and concentrates instead on the sole criterion of cost; (2) competitive bidding could lead to a reduction in competition in a locality and resultant monopolistic practices through loss leader pricing situations and marketing strategies; (3) competitive bidding could affect timeliness of services by increasing turnaround time which will inevitably increase costs for patient services.

It has long been the position of the college that the delivery of clinical laboratory services is the provision of medical services. The physician-director of a clinical laboratory is dedicated to the provision of quality laboratory services at a reasonable cost to the patient; not "cost effective" laboratory services at a reasonable level of quality.

The college believes that the determination of the cost of a laboratory service is a very complex issue. If this determination is to be done in a meaningful way, one must evaluate all the elements of cost associated with the testing process and consider the cost and value of what happens as a result of that testing.

What will the guidelines be for soliciting, processing, and awarding bids? Will they be awarded by the procedure? By service to the recipient? By the year? By the region?

We have raised these numerous problems associated with competitive bidding each time we have presented testimony on CLIA. It is interesting to note that the House Commerce Committee, in its report on H.R. 10909, raises a number of concerns similar to those expressed by the college. We do concur with the committee on these possible problems. We do not agree with the committee that the alleged benefits of competitive bidding outweigh the possible adverse consequences.

Mr. Chairman, although other sections of the bill do not directly amend the Social Security Act, we would like to offer comment on two subjects—highly specialized laboratories and proficiency testing.

We believe their inclusion will have an adverse impact on the financial integrity of the social security trust fund, and further that these provisions could result in increased cost of services to medicare beneficiaries without an increase in the quality of those services.

Section 372(c)(5) provides an exemption for clinical laboratories "engaged exclusively in the assessment of cardiac or pulmonary function." The college emphatically believes that the retention of this exemption in its broadest interpretation will lead to the fragmentation of the clinical laboratory and could lead to a decline in the quality of laboratory services.

We do not dispute the right of laboratories performing cardiac or pulmonary assessment to perform tests. We do, however, dispute the exemption from national standards.

Mr. Chairman, the major function of the heart is to provide blood and oxygen to tissues. Would not the performance of blood hemoglobins, the most widely performed test in this country, be an assessment of cardiac function and exempt from national standards under this section? Would this provision encourage clinical pathology laboratories to fragment their services for regulatory purposes? Unfortunately we must answer yes to these questions.

We do not believe procedures should be covered by regulation based solely on the location of their performance. Standards should not apply to testing procedures in one area of an institution, but not to the same procedures performed in another area.

In explaining the reasons for granting this exemption, the House Commerce Committee, in its report, may be creating a Pandora's box. The report states that the Secretary "may need to exercise flexibility in what he determines constitutes a physician's office." Then follow several examples which we interpret to mean that a physician specialist, be it anesthesiologist, cardiologist, or intensivist, could consider his/her place of practice; that is, recovery room, as a "physician's office" for the purpose of the act; thereby possibly exempting such place of practice. We would expect a logical extension of such thought to conclude that a pathologist, being a highly specialized physician, could consider the clinical pathology laboratory his/her "physician's office" and therefore be exempt from the provisions of the act.

In summary, Mr. Chairman, we believe the retention of this section will lead to a proliferation of "splinter labs" classed as physicians' offices.

Mr. Chairman, the bill contains provisions which require annual onsite proficiency testing and optional blind proficiency testing of clinical laboratories.

Proficiency testing is a tool to be used by laboratories as a part of a program to maintain and improve quality of services and to make it possible to compare the performance of the laboratory against similar laboratories across the country. The college conducts a proficiency testing program that serves both of the above-stated functions.

The college is strongly opposed to a national system of onsite proficiency testing. Logistically, onsite proficiency testing requires that a qualified inspector carry a sample or samples onto the premises of a laboratory and remain there until the analyses are complete. In order for the testing process to be valid, the inspector must be a qualified individual with proper scientific and technical background.

If the proficiency of the laboratory is to be adequately tested, then a sampling of the range of the tests performed must be assessed. Some laboratory procedures may take 3 to 4 hours to complete, many average 1 to 2 hours. Some tests, especially in the areas of parasitology and bacteriology, may take 2 to 3 days to complete; some over a week.

The problems of cost are easily related to these logistical problems.

The consideration of costs raises the question, "Who will shoulder the burden?" The answer is that this specifically unknown, but substantial, amount will be borne by the already strained social security trust fund.

The college would like to register strong opposition to the inclusion of a provision calling for blind proficiency testing. Our position is based on the belief that a national system of blind proficiency testing is neither practical, possible nor desirable.

The question of blind proficiency testing was discussed in October 1975 at a National Conference on Proficiency Testing. A number of recommendations resulted from the conference. One of those recommendations was:

> Blind and onsite proficiency testing may be useful in certain special circumstances but routine widespread application is precluded by insurmountable logistic and cost problems.

Mr. Chairman, we oppose both universal blind and onsite proficiency testing on similar grounds—prohibitive cost and difficult logistics. We would suggest that onsite and/or blind proficiency testing programs be used only in those instances where there are indications that a laboratory is engaging in fraudulent practices.

Mr. Chairman, this concludes our oral testimony. We have included specific amendments to the bill in our written statement. We thank you for affording us the time to present our views on this important legislation, and we will be happy to respond to questions.

[The statement and attachments follow:]

STATEMENT OF THE COLLEGE OF AMERICAN PATHOLOGISTS

Mr. Chairman, and Members of the Committee, I am Tyra T. Hutchens, M.D., President of the College of American Pathologists. With me today are Roger K. Gilbert, M.D. and Jerald R. Schenken, M.D.

Mr. Chairman, we appear here today to represent the College of American Pathologists—and to present the views of the College on H.R. 10909, the Clinical Laboratory Improvement Act of 1978.

The College of American Pathologists (CAP) is a nonprofit, voluntary, medical specialty organization, headquartered in Skokie, Illinois. The CAP was founded in 1947, and has more than 7,500 physician-members who practice the medical specialty of pathology. CAP Fellows are certified by the American Board of Pathology.

Our members practice in hospitals, independent medical laboratories, medical schools, military institutions, and various facilities of federal, state and local governments. In addition, our members work in medical laboratory research institutions.

We welcome the opportunity to appear before you and the Committee to comment on the proposed Clinical Laboratory Improvement Act of 1978. The College of American Pathologists has a proud record of leadership in advancing the quality of work performed in clinical laboratories throughout the United States.

H.R. 10909 contains features which the College supports. However, it also contains features which, in our view, could needlessly increase the administrative burden to both government agencies and clinical laboratories. In addition, some of these features will unnecessarily escalate the cost of laboratory services at a time when "cost containment" is a major concern, and more importantly, they may have an adverse effect on the quality of laboratory services.

Therefore, we offer the Committee what we believe to be constructive comments on specific sections of the bill. It is our opinion that the embodiment of our suggestions will make the legislation more effective in achieving the objective of better laboratory service.

At the outset we would like to state the standard of work of the majority of clinical laboratories in the United States to be outstanding and unequalled by any other nation. This statement is supported by extensive published data based on the work of the vast majority of U.S. laboratories.

We are proud to note that the quality of laboratory service has advanced progressively during the past decade as new technology and procedures have been introduced. Indeed, high quality laboratory services are in the best interest of both the patient and the profession. Furthermore, the delivery of high quality laboratory services is the most effective way to control costs.

We recognize the need to update legislation which is now over ten years old; however, we do believe that any revisions should be directed at solving clearly defined problems. Historically, the College has supported legislation aimed at providing realistic, practical and economically achievable ways to assure quality laboratory services to patients. When we have been critical of legislation dealing with the clinical laboratory, our chief aim has been to call attention to legislative provisions which we believed would fall short of their objectives.

We would now like to offer comments and suggestions concerning specific provisions of the proposed legislation.

AMENDMENTS TO THE SOCIAL SECURITY ACT

Mr. Chairman, the College strongly believes amendments dealing with reimbursement under government financed health care programs best belongs in separate legislation. The College has testified to this point before several Committees of both the House and the Senate. In addition, we have gone on the record in support in principle of at least two bills containing amendments to the Social Security Act—The Medicare-Medicaid Anti-fraud and Abuse Amendment of 1977 (P.L. 93–142) and S. 1470, The Medicare-Medicaid Administrative and Reimbursement Reform Act. We cite this to show that we are not opposed to reimbursement amendments to the Act where warranted. However, we do oppose their inclusion in this bill. Inclusion of such provisions in H.R. 10909 may serve to compound the confusion surrounding such payment systems which are under intensive scrutiny by both the Congress and the Administration. Perhaps more importantly, the inclusion of reimbursement amendments detract from the primary purpose of the bill—improved quality of services. However, if such amendments remain in H.R. 10909 we offer the following comments.

Billing Procedures (Section 202)

The College supports the concept of this section which is in reality a procedure commonly termed "disclosure billing". In testimony and in statements (on proposed regulations) to the Secretary, DHEW, the College has urged that when physicians have laboratory services performed outside of their offices, the physician identify the laboratory providing the services and the amount charged to or paid by the physician be noted on the physician's bill upon request for payment.

Section 205 of H.R. 10909 provides for a two-year study of billing practices for laboratory services. While we do not object to this study, we question

its necessity in light of on-going programs of DHEW. Project Integrity, a program designed to detect fraud and abuse in government-financed health care programs, is at this time finalizing procedures for an audit which when completed could provide information similar to that which could result from the study envisioned in Section 205.

We believe that Section 205 is unnecessary and duplicative of efforts being initiated by the Secretary of DHEW.

Study of Financial Arrangements (Section 204)

The College questions the need for the study called for in this section. The limitation of this study only to arrangements for the provision of laboratory service appears, in our opinion, discriminatory.

The College has presented testimony to the Subcommittee on Health of the Senate Finance Committee which shows that the charges for laboratory services, are not related to the contractual arrangement existing between the hospital and its pathologist(s).

The Arthur Anderson Co., under a contract issued by the Social Security Administration, has recently concluded an 18 month study on financial arrangements of hospital-based physicians with 120 hospitals. In our opinion, the report is inconclusive.

At the present time, the Health Care Financing Administration is considering the issuing of contracts and/or grants to nongovernment organizations to carry on studies dealing with hospital-based physician reimbursement.

In our opinion, the study called for in the legislation would be duplicative of these efforts.

We would, therefore, recommend that this section be deleted from the bill.

If, however, this Committee feels that such a study is needed and necessary, then we would make the following recommendations:

(1) The Section be deleted from this bill and be included in appropriate legislation dealing with hospital cost containment;

(2) The time frame of the study be extended to a 24 month period;

(3) The study scope be extended to include services provided to hospital patients by all hospital-based physicians and other providers under arrangement;

(4) That provisions limiting percentage contracts and/or lease arrangements contained in pending legislation on hospital cost containment be held in abeyance until such a study is completed.

Competitive Bidding (Section 203(a) (1) and (2))

The College has testified on several occasions in opposition to competitive bidding as a method of providing laboratory service to beneficiaries. Our position has not changed. We foresee a serious degradation of quality in the delivery of laboratory services to Medicaid beneficiaries under competitive bidding. We strongly believe that a number of major problems would exist under competitive bidding: (1) competitive bidding ignores a primary aspect of laboratory services—quality—and concentrates instead on the sole criterion of cost; (2) competitive bidding could lead to a reduction in competition in a locality and resultant monopolistic practices; (3) competitive bidding could result in loss leader pricing situations and marketing strategies; (4) could affect timeliness of services by increasing turn around time which will inevitably increase costs for patient service.

It has long been the position of the College that the delivery of clinical laboratory services is the provision of medical services. The choice of a laboratory by an attending physician is a function of that physician in providing medical services to his/her patient. The physician-director of a clinical laboratory is dedicated to the provision of quality laboratory services at a reasonable cost to the patient; not "cost-effective" laboratory services at a reasonable level of quality. We believe that competitive bidding either forces laboratory to provide the latter type of service or forces from the marketplace the laboratory unwilling to compromise quality. Thus, we fear that competitive bidding will be devastating to laboratories attempting to provide a broad spectrum of truly quality laboratory services.

The College believes that the determination of the cost of a laboratory service is a very complex issue. If this determination is to be done in a meaningful way, one must evaluate all the elements of cost associated with the testing process and consider the cost *and* value of what happens as a result of that testing. The costs directly associated with testing a specimen, listed below, may represent only a minor component of total cost.

Direct Costs

1. Instrument purchase or lease.
2. Instrument maintenance.
3. Quality Control programs.
4. Payroll and fringe benefits.
5. Reagent and standards.
6. Supplies.
7. Overhead.

We believe that competitive bidding would consider these costs as being the only cost of performing a laboratory service. This is just not the case.

Associated costs, shown below, are an indispensible part of the testing process. The total of these associated costs may exceed the cost of running the tests. Studies have shown that high volume automated laboratories may be able to perform some laboratory tests for a relatively low cost, but when associated costs are added, the cost of the laboratory procedure from some high volume automated laboratories may be more than that from a comprehensive physician-directed service laboratory.

Associated Costs

1. Producing and transmitting the requisition.
2. Obtaining, processing and transporting the specimen.
3. Evaluating, interpreting, transmitting and filing the report.
4. Data processing.
5. Billing and collecting fees.
6. Bad debts.

The costs listed below, which we shall term related costs, are costs that are related to what happens as a result of the performance of the test procedure. The College firmly believes that a clinical laboratory service is not complete unless the services below are provided when necessary.

Related Costs

1. Retesting for equivocal results.
2. Follow-up testing of positives.
3. Related diagnostic procedures.
4. Physician examination and consultation.
5. Medical and surgical therapy.
6. Therapeutic monitoring.
7. Therapeutic follow-up and retesting.

In each element of cost, there must be recognition given to the professional input cost of medical direction, supervision and responsibility provided at all levels by the pathologist.

In a letter to the Journal of American Medical Association (Vol. 237, No. 9) submitted by officials of the Pennsylvania State Bureau of Laboratories, the authors make a statement referring to the problems of competitive bidding; "All too often the only criterion applied to the selection of a laboratory is cost of services, and this has frequently proved to be a tragic mistake. In situations where competitive bidding for toxicologic laboratory services is the policy, it may be difficult or impossible to obtain suitable analytical services unless other requirements are imposed."

There is little doubt that competitive bidding will lead to a reduction in competition in the given locality due to the fact that many laboratories will not be able to offer quality services competitive in price with large automated laboratories. This loss of competition will result in many of the costs normally associated with monopolistic or oligopolistic markets—loss of jobs, loss of innovation, and provider dominated supply as regards quality and quantity.

What will the guidelines be for soliciting, processing and awarding bids? Will they be awarded by the procedure? By service to the recipient? By the year? By the region? Will not this encourage price wars, loss leaders and other strictly commercial efforts at destuctive competition to enter into and ultimately dominate the clinical pathology laboratory?

We have raised these numerous problems associated with competitive bidding each time we have presented testimony on CLIA. It is interesting to note that the House Commerce Committee, in its report on H.R. 10909, raises a number of concerns similar to those expressed by the College. Indeed we do concur with the Committee on these possible problems. We do not agree with the Committee that the alleged benefits of competitive bidding outweigh the possible adverse consequences.

In commenting on the quality of laboratory services, the Committee report states:

"The Committee is concerned, however, that concentration of Medicaid business in a small number of laboratories might prove detrimental to quality if the laboratory served only the Medicaid population."

The Committee also expressed concerns over possible resultant monopolistic practices:

"The Committee recognizes that one result of this legislation will be a reduction in the number of providers from whom a State, or political subdivision, purchases laboratory services. Theoretically, it would be possible for a State or political subdivision, under this act to enter into arrangements with only one provider of laboratory services in an area . . ."

We urge the deletion of Section 203(a) (1) and (2). If the Committee does not agree with our position then we suggest that the Committee adopt the competitive bidding provision contained in S. 705, the Senate-passed CLIA. S. 705 provides for only a one-year demonstration project for competitive bidding. We believe this one-year time limitation is for more appropriate than the three-year period granted in H.R. 10909.

Mr. Chairman, although other sections of H.R. 10909 do not directly amend the Social Security Act, we would like to offer comment on highly specialized laboratories and on-site and blind proficiency testing. In addition we offer very brief comments on several other provisions of the bill.

We offer these comments because we believe their inclusion, as presently contained in H.R. 10909, will have an adverse impact on the financial integrity of the Social Security Trust Fund, and further that these provisions could result in increased cost of services to Medicare beneficiaries without an increase in the quality of those services.

HIGHLY SPECIALIZED LABORATORIES

Section 372(c)(5) provides an exemption for clinical laboratories "engaged exclusively in the assessment of cardiac or pulmonary functions." The College emphatically believes that the retention of this exemption in its broadest interpretation, will lead to the fragmenting of the clinical laboratory and could lead to a decline in the quality of laboratory services.

We do not dispute the right of laboratories performing cardiac or pulmonary assessment to perform tests. We do however, dispute the exemption from national standards.

A question central to the issue is, what is the assessment of cardiac and pulmonary functions? Broadly defined (as the bill allows), it could include the assessment of a variety of organic functions which secondarily impact on cardiac and pulmonary function. A case in point is the laboratory workup for hypertension, obviously involved in cardiac function. Some organic causes for hypertension are renal and adrenal diseases. By definition, H.R. 10909 would then exempt whole sections of a laboratory such as those measuring catecholamines and their metabolites and renal function tests. In addition, the evaluation of electrolytes are necessary for a complete diagnosis of pulmonary and cardiac patients. Another case in point is the need of acutely ill cardiac patients for controlled laboratory reporting and performance of a number of enzyme analyses. The creation of an exemption for these assays will remove from regulation a significant portion of an active clinical laboratory's workload, and in effect says that acute care laboratory work (some of the most critical measurements) is exempted from national standards.

Mr. Chairman, the major function of the heart is to provide blood and oxygen to tissues. Would not the performance of blood hemoglobins, the most widely performed test in this country be an assessment of cardiac function? Would this provision in H.R. 10909 encourage clinical pathology laboratories to fragment their services for regulatory purposes? Unfortunately we must answer yes to these questions.

We do not believe procedures should be covered by regulation based solely on the location of their performances.

In this country, blood gas measurements are performed in independent units in association with other assessment of cardiac and pulmonary function as well as in central clinical laboratories. This is due, in the main, to the establishment of satellite acute care blood gas laboratories near intensive care and surgical/recovery units. Our concern is not with the existing satellite blood gas units, be-

cause they are often under the control and direction of the central laboratory. Rather, our concern rests with the possible proliferation of totally independent and unregulated units. A dual system of regulation would exist. By no means are all blood gas functions performed in satellite units. Many measurements are performed at a central laboratory which would have to meet regulations while the satellite laboratory would operate independently and without regulatory standards.

In summary, the rationale for this exemption is very dubious. It exempts two major areas of current clinical laboratory work. It exempts a group of procedures the limits of which cannot realistically be clearly defined, because neither the heart nor lungs are detached from other organ systems of the body. It further exempts from National Standards these two critical areas of patient care (i.e. Cardiac and Pulmonary function testing) both of which need standards. It is a fact that clinical laboratories have become sophisticated enough that virtually no clinical pathology laboratory testing would fall under "highly specialized" and outside the scope of the clinical laboratory except those laboratories doing exclusively in vitro studies such as scanning. Standards should not apply to testing in one area of an institution but not to the same testing performed in another. The suggestion that research or "newness" should exempt in-vitro testing of pulmonary and cardiac patients in not justified as a general policy.

In explaining the reasons for granting this exemption, the House Commerce Committee, in its report on H.R. 10909 (page 17), may be creating a potential open Pandora's Box. The report states that the Secretary "may need to exercise flexibility in what he determines constitutes a physician's office." Then follow several examples which we interpret to mean that a physician specialist (be it anesthesiologist, cardiologist or intensivist) could consider his/her place of practice, e.g., recovery room, as a "physician's office" for the purpose of the act; thereby possibly exempting such place of practice. We would expect a logical extension of such thought to conclude that a pathologist, being a highly specialized physician, could consider the clinical pathology laboratory his/her "physician's office" and therefore be exempt from the provisions of this Act. Could not virtually all the laboratories in the nation's approximately 7,500 acute care hospitals which are directed by pathologists be exempt as physician's office laboratories?

In summary, Mr. Chairman, we believe the retention of Section 372(c) (5) will lead to a most objectionable proliferation of "splinter labs" classed as physicians' offices. Thus, we strongly urge that this exemption be removed from H.R. 10909. If this is not possible, then we suggest the language be developed which would strictly limit such exemption. One possible amendment would have Section 372(c) (5) read: ". . . shall not apply to any clinical laboratory engaged exclusively in highly specialized in vivo procedures for the assessment of cardiac or pulmonary function."

Section 104 of H.R. 10909 provides for a study and report on highly specialized clinical laboratories. The College believes the wording of this section is too nonspecific to clearly focus on the problem of exempting highly specialized laboratories performing cardiac and pulmonary assessments. As this section is now worded, the Secretary would make determinations as to whether a procedure is highly specialized. This could quite easily result in numerous different sets of individually tailored standards for laboratories, e.g., nuclear medicine, neonatal, cardiac/pulmonary, infectious disease, and others. We believe the wording should be clear that such study is limited to those laboratories that would be granted an exemption under Section 372(c) (5). We would recommend that in lieu of granting an exemption, that the standards be applicable to such laboratories during the two-year study period, and at the conclusion of the study, adjustments be made if needed. By doing this, the dangers of the fragmentation of clinical laboratories and the lack of quality control over a number of testing procedures would be obviated.

PROFICIENCY TESTING AND ON-SITE INSPECTIONS

Mr. Chairman, H.R. 10909, contains provisions which require annual on-site proficiency testing of clinical laboratories and optional blind proficiency testing of clinical laboratories.

Proficiency testing is a tool to be used by laboratories as a part of a program to maintain and improve quality of services and to make it possible to compare the performance of the laboratory against comparable laboratories across the country. The College conducts a proficiency testing program that serves both of the above stated functions.

The College also has an inspection and accreditation program in which an extensive on-site inspection of the laboratory is made. The inspection team, composed of pathologists and medical technologists, performs a physical inspection of the laboratory; reviews record keeping and quality control procedures; and observes the performance of procedures. These programs, proficiency testing, and inspection and accreditation are, as you can see, two distinct programs.

H.R. 10909 appears to cloud that distinction. On-site proficiency testing, as required in Section 371(d) is tied to Section 376(d)(1) and (2) of the bill which are procedures for enforcement of the Act through inspection of the laboratory. We do not believe this to be appropriate.

We support on-site inspection. We have been a leader in its development and application. However, we believe on-site inspection, like proficiency testing, is a tool to be used in assuring quality laboratory services. For this reason, the College suggests that language be included in H.R. 10909 which would make on-site inspection a standard for assuring quality.

Specifically, we suggest that Section 371(b)(1)(c) be reworded as follows:

"Satisfactory performance in a proficiency testing program and in an on-site inspection program conducted by qualified public or private nonprofit entities which have adopted standards at least as stringent as those in effect in this section. Under agreements in Section 377(a), participation in such private nonprofit programs may be used in lieu of Federal or State-operated programs."

This placement of this wording makes clear the role of proficiency testing and inspection. In addition, we urge that Section 371(d) be stricken and the language which appeared in H.R. 6221 as reported by the House Commerce Subcommittee on Health (Section 353(b)(3)) be reinstated.

The College is strongly opposed to universal unannounced on-site proficiency testing and blind proficiency testing.

It should be clear, however, that we do support on-site inspection of laboratories and would support on-site or blind proficiency testing limited to suspected cases of fraud.

Mr. Chairman, the College has participated with both Federal and State government in upgrading the quality of laboratory services through agreements granting equivalency to College programs of inspecting and accrediting interstate laboratories. This agreement was formulated under the provisions of the Clinical Laboratory Improvement Act of 1967. We wish to continue in our role of providing services which are equivalent to regulatory requirements under law. However, the wording in H.R. 10909 is such that equivalency would not be granted unless an organization were capable of providing universal on-site and blind proficiency testing to all regulated laboratories. In other words, it is an all or none situation. Because of what we believe to be the prohibitive costs associated with operating blind and/or on-site proficiency testing, it will be most difficult to meet these requirements. Thus a program which we believe has benefited the laboratory practitioner, the patient, and the government, may, by necessity, end.

We therefore urge that language be included in either the bill or the Committee Report, giving the Secretary flexibility in granting equivalency to nonprofit organizations which would remove the "all or none" implication.

On-Site Proficiency Testing

The College is strongly opposed to a national system of on-site proficiency testing. Logistically, on-site proficiency testing requires that a qualified inspector carry a sample or samples onto the premises of a laboratory and remain there until the analyses are complete. In order for the testing process to be valid, the inspector must be a qualified individual with proper scientific and technical background. If not, he/she would have no idea as to the correctness of the procedure taking place.

Much attention has been given to the stated success of the on-site proficiency testing program in New York City. However, a critical factor is often overlooked. The large number of laboratories in the city are geographically very close; thereby reducing travel time and the necessary number of inspectors. If a comparable program were implemented on a state-wide basis, an unreasonably large number of qualified inspectors would be required to be on the road virtually all the time. If the on-site program is to apply to all clinical laboratories (approximately 13,500), the number of qualified inspectors needed would be multitudinous.

If the proficiency of the laboratory is to be adequately tested, then a sampling of the range of the tests performed must be tested. Some laboratory procedures may take 3–4 hours to complete—many average 1–2 hours. Some tests, especially in the areas of parasitology and bacteriology, may take 2–3 days to complete; some over a week. In addition, many laboratories may run automated tests that can be batched on only one or two days per week.

The number of qualified inspectors that would be needed, the wide geographical distances separating laboratories in many parts of the country, and the complexity and the time consuming nature of a variety of laboratory procedures present severe logistical problems that would seriously hamper, if not prevent, the application of an on-site proficiency testing program on a nation-wide basis.

The problems of cost are easily related to the above stated logistical problems. The salary expense of the great number of inspectors needed would be enormous. The situation is compounded when the cost of travel and lodging are added in those geographically dispersed areas. The fact that inspectors may spend many nonproductive hours just waiting for tests to be completed is anything but cost effective.

Other costs associated with on-site testing are the need for sophisticated proficiency testing samples that must be able to withstand the rigors of time and travel without deterioration. The number of such samples necessary makes the consideration of cost most important. If on-site testing is to be used as a tool of interlaboratory comparison, then the samples must meet national criteria that would make possible the comparing of national results.

How will assay results of the samples be kept confidential. Will the inspectors have multiple samples to choose from? How can we assure sample stability, accuracy and interpretability? Can all laboratories be treated fairly and equally? Can we prevent massive litigation arising from this process? Won't the educational value be destroyed? How will the results be used?

The consideration of costs begs the question, "who will shoulder the burden?" The answer is that this specifically unknown, but substantial amount, will be borne by the already strained Social Security Trust Fund.

Blind Proficiency Testing

The college would like to register strong opposition to the inclusion of a provision calling for blind proficiency testing. This position is based on the belief that a national system of blind proficiency testing is neither practical, possible nor desirable. The term itself is ambiguous and open to many substantially different interpretations. We would be happy to provide the Committee with information about the problems and consequences of attempts at blind surveying.

The question of blind proficiency testing was discussed in October of 1975 at a National Conference on Proficiency Testing held in Washington, D.C. under the sponsorship of the National Council on Health Laboratory Services (NCHLS). The NCHLS is a broadly based group which includes both federal and state agencies and private professional organizations. A number of recommendations resulted from the conference. One of those recommendations was:

"Blind and on-site proficiency testing may be useful in certain special circumstances but routine widespread application is precluded by insurmountable logistic and cost problems."

Two statements, one by a New York City Health Department employee and the other a member of the staff of the Center for Disease Control, support this recommendation:

Sylvia Blatt, M.S.—New York City Department of Health, "in order to determine the actual quality of daily testing, it would be necessary to send blind specimens through the usual channels. However, this would be extremely expensive and would require the cooperation of medical practitioners."

Louis C. LaMotte, Sc.D.—Center for Disease Control, "This type of testing (blind) is expensive and difficult to arrange, but it is particularly revealing. Although impractical on a regular basis with presently available technology, this approach does appear to determine how well the staff performs under conditions approximating those prevailing with patient specimens."

Mr. Chairman, we oppose both universal blind and on-site proficiency testing on similar grounds—prohibitive cost and difficult logistics.

We would therefore recommend that the amendment to Section 371(d), passed by the Interstate and Foreign Commerce Committee be deleted.

Mr. Chairman, we would suggest that on-site and/or blind proficiency testing programs be used in those instances where there are indications that a laboratory is engaging in fraudulent practices. To require such a program of all laboratories would be immensely costly and would offer little, or no assurance that laboratory performance will be enhanced to any great extent.

AUTHORITY OF THE SECRETARY

Before we conclude our statement with very brief comments on several other sections of the bill, we would like to raise an important question. Does not the power given to the Secretary in Section 370(b)(1)(G), to promulgate national standards which "include such other requirements as the Secretary determines necessary to assure consistent performance by such laboratories of accurate and reliable services", preclude the specificity of language in the bill regarding highly specialized laboratories and proficiency testing? We urge that the Committee consider carefully the possibility of relying on that section and on Committee Report language to require the Secretary to work closely in conjunction with appropriate professional organizations in efforts to develop programs in these areas that are equitable to the government, the Medicare beneficiary, and the provider.

Laboratory Definition—(Section 370(1)(A))

The College is concerned that blood banks have been excluded from the definition of a clinical laboratory under this Act. We consider the hospital blood bank to be an integral component of the hospital laboratory. In this context there is little justification for a blood bank to fall under the jurisdiction of another federal agency and under another set of regulations. A major intent of H.R. 10909 is to bring uniformity to the regulation of laboratories. By excluding blood banks, H.R. 10909 is taking a step backward toward fragmentation.

Research Laboratories (Section 372(c)(4))

The College supports an exemption for laboratories engaged exclusively in biomedical or behavioral research.

Agreements (Section 377)

The College is in support of this section which provides an opportunity for nonprofit entities such as the College to develop or continue existing programs which have standards as stringent as those developed by the Secretary and/or the state.

Our understanding of the term "enter into agreement with" in this section will permit the Secretary and the states to utilize the programs of qualified nonprofit entities as an alternative to federal and state programs. To clarify this understanding, we would suggest adding a new paragraph (4) to 373(a). Such subsection would read: "(4) The inspection and proficiency testing programs of private nonprofit entities which are deemed to be equal to or more stringent than those developed by the Secretary or states may be utilized in lieu of federal or state programs for the purpose of carrying out those activities described in subparagraphs (1), (2) and (3)."

The Inspection and Accreditation Program of the College is the only program of a non-government entity to have been recognized as equivalent to Federal programs under the Clinical Laboratory Improvement Act of 1967.

CONCLUSION

Mr. Chairman, a primary mission of the College of American Pathologists is to ensure the delivery of high quality laboratory services at a reasonable cost to the patient.

We believe that sections of H.R. 10909 will enhance this mission of the College and thus we strongly support these sections. However, we just as strongly oppose those sections which we believe will diminish the quality of laboratory services or fragment the delivery of such services.

Mr. Chairman, this concludes our formal testimony. We thank you for affording us the time to present our views on this important legislation and we will be happy to respond to questions.

APPENDIX A

Brief Description of College of American Pathologists Laboratory Improvement Program

The College of American Pathologists (CAP) is a nonprofit, voluntary, medical specialty organization, headquartered in Skokie, Illinois. The CAP was founded in 1947, and has more than 7,000 physician-members who practice the medical specialty of pathology. CAP Fellows are certified by the American Board of Pathology.

Our members practice in hospitals, in independent medical laboratories, in medical schools, in military institutions, and in various facilities of Federal, state and local governments. In addition, our members work in medical laboratory research institutions.

PROGRAMS OF THE COLLEGE

As a leader in laboratory medicine, the College has developed valuable scientific, technical and educational programs for use by pathologists and other laboratorians to assist them in their professional practice. The primary goal of these programs is to seek excellence in laboratory services, thereby improving patient care.

These programs have a direct bearing on laboratory excellence, quality assurance and high-level performance. Some of these programs are:

Inspection and Accreditation Program.

Survey Programs (an inter-laboratory comparison, or proficiency testing system).

Quality Assurance Service (an internal quality control system for use on a day-to-day basis).

Workload Recording Method (a management system for evaluation of laboratory productivity).

Instrument Maintenance (a program for the routine preventive maintenance of instruments in laboratories).

Systematized Nomenclature of Pathology—SNOP—(A universal language for recording and reporting the activities of a laboratory).

Systematized Nomenclature of Medicine—SNOMed—(A universal terminology for all of medicine).

Product Evaluation Program.

Educational Seminars in Management, Laboratory Improvement, etc.

Publications and audio-visuals on Standards, Quality Control, Laboratory Design, and Patient Education.

Because some members of government and the news media have suggested that laboratory testing and performance are inadequate, the College believes that it must take the time now to explain what a single, major pathology association has done, and is doing, to raise laboratory services and standards from their already high levels to even greater heights.

Our main emphasis will be the College's Inspection and Accreditation program and the Survey Programs because these two programs are directly related to the provisions of CLIA '67 and the proposed legislation.

INSPECTION AND ACCREDITATION PROGRAM

The Laboratory Inspection and Accreditation program of the College was established in 1960. Its primary goal was, and is, to develop optimum and dynamic quality standards for the clinical laboratory and to review and evaluate the laboratory against these standards.

The Inspection and Accreditation program's initial standards checklist consisted of one page of suggested areas to be reviewed in the medical laboratory. After a group of laboratories was inspected under this method, the inspectors (all certified pathologists) suggested that a more comprehensive standards checklist should be developed as a guideline for laboratory inspection. Over the past 15 years, the standards checklist has been continually revised, expanding from the original one-page set of guidelines to the current set of nine booklets containing more than 2,000 questions for evaluation purposes. The checklist is a comprehensive guide for the inspector to assure a review of all aspects of the standards.

In 1969, a comprehensive computer system was developed to schedule, monitor and evaluate this inspection process. This system now includes a comprehensive evaluation of the 2,000 questions within the current checklist, which

automatically prints out: (1) a corrective statement for each unacceptable result noted; (2) a weekly progress report of the laboratories currently in the process of inspection (copies of this report are sent to many government agencies, such as the Veterans' Administration and the Center for Disease Control), and (3) a weekly report of all laboratories within the program, and (4) coded labels which indicate an appropriate reminder letter, when necessary, to insure a continuous flow of activity within the inspection process.

One of the conditions for accreditation is the successful participation in the appropriate College Survey Programs (Proficiency Testing). The primary reason for this condition is to document testing performance and to serve as a continuous monitor of the laboratory. Both the Inspection and Accreditation program and the Survey Programs form one total continuous evaluation program for the medical laboratory.

The computerized "Cumulative Survey Management Report" has been developed to aid in monitoring Survey results. This report notes all exceptions within the College's Survey Programs for the previous two-year period, and detects trends and possible problem areas of testing within the laboratory. It is recorded by computer on a quarterly basis and evaluated by the appropriate CAP I & A Commissioner. Guidelines and standards have been developed for the evaluation of these trends, and specific information is required from the laboratory director before its accreditation status is continued in these areas.

The CAP Inspection and Accreditation program is more stringent than those developed through regulation. Before a laboratory is accredited by CAP, it must institute measures which will correct all Phase II deficiencies found in the on-site inspection of the total laboratory operation. The College's I & A program does not accredit portions or sections of a laboratory. This policy also applies to laboratories in interstate commerce which hold a "Letter of Exemption" based on their College accreditation. In addition, each individual test in the Survey Program is judged for performance (not just a section such as Chemistry).

It is important to note that no laboratory has been accredited under this program by a grandfather clause.

The laboratory standards are monitored through a checklist which is used for each sub-discipline in the laboratory. These are:

Section I—Laboratory General, which includes professional and administrative activities.
Section II—Hematology.
Section III—Chemistry.
Section IIIA—Urinalysis.
Section IV—Microbiology.
Section V—Blood Bank.
Section VI—Diagnostic Immunology and Syphilis Serology.
Section VII—Nuclear Medicine (Includes radiobioassay).
Section VIII—Anatomic Pathology and Cytology.
Section IX—Cytogenetics.

The I & A Program has taken into consideration all changes in regulations. New regulations, as issued for Medicare, OSHA, CLIA '67, state licensure, FDA requirements for blood banking and product labeling, and other governmental regulations affecting the practice of laboratory medicine, have been included in questions on the standards checklist.

The Inspection and Accreditation Program has been reviewed annually and declared to be equivalent to the standards established by the Secretary (DHEW) since passage of CLIA '67.

The standards developed by the CAP Commission on Inspection and Accreditation are the product of 16 years of constant review and modifications in response to rapid technological, scientific and regulatory changes in the medical specialty of pathology. The standards have influenced and have been influenced by, all laboratory standards and regulations of other organizations and governmental agencies. The standards remain the same for any laboratory—large or small, hospital or independent, interstate or intrastate—for excellence in all laboratories that seek our accreditation.

The program is directed administratively at the College's Headquarters Office in Skokie, Illinois. It is operated by a commission of 12 board-certified pathologists, who serve without pay as commissioners for specific regions across the country. These commissioners are assisted by individual state commissioners of deputies in the function of assigning and scheduling some 500 pathologist-in-

spectors, who practice in an accredited laboratory and have attended an inspection seminar. The average total professional time involved per inspection is 70 man-hours. All of these man-hours are donated voluntarily. An average of 800 laboratories are inspected per year, requiring approximately 56,000 donated man-hours per year.

The I & A Program is national in scope. Laboratories in every state participate, including government laboratories under contract, such as 168 Veterans Administration laboratories, 33 Army laboratories, and 30 Navy laboratories.

The program represents participation not only by hospital laboratories, but also by independent and commercial laboratories across the country. They range in size from small laboratories and privately owned clinics to large university complexes. The program not only evaluates the technical competence, but also the managerial and professional expertise provided in the operation of a medical laboratory. Such functions of the laboratory director as his contributions to the medical community as a consultant and as a critical participant on many of the valuable medical staff committees of hospitals also are reviewed.

Currently 1,376 laboratories are accredited and approximately 300 are in the process of being inspected or accredited. Accreditation is granted only when the operation of the laboratory meets the standards of the Commission on Inspection and Accreditation. Of some 1,500 laboratories that have been in the College's I&A Program, approximately 80 laboratories have been denied accreditation to date for not meeting the standards.

Through the Inspection and Accreditation Program, improvement in laboratory performance has been shown.

In 1970, deficiencies (Phase II) totaled 10.2 percent. In 1974, there were only 4.7 percent such Phase II deficiencies, (deficiencies which may affect patient care through that laboratory's performance).

The success of the program is attributable to the voluntary professional interest and expertise. Laboratories requesting voluntary accreditation desire to improve and meet the high standards of excellence set by the Commission. The program is not merely a preparation for a one-day inspection, but is a continuing daily way of operating in the laboratory. Laboratory directors look upon the I&A Program as a day-to-day, week-to-week mechanism for properly managing, operating and performing laboratory tests for patient care. The inspectors do not participate because they want to be regulars, but because they sincerely believe they are providing a valuable service for achieving excellence in laboratory medicine. It is an educational and professional exchange between the inspector and the inspected. It provides for new and exciting modifications within the program because the inspected and the inspectors do have input into the system for change, improvement and clarification.

The program does not have to depend on new legislation or regulation to act on a void or a modification within the system or standards. If a change is approved, it is instituted and communicated to those involved immediately. The program also reacts quickly to regulatory change for modification of the system. All in all, it acts and reacts to maintain excellence.

The I&A Program was instituted before Federal and State cost regulations were implemented. It was developed to meet, perpetuate and foster excellence in laboratory standards. Participation on any basis is not a pass or fail experience, but a total commitment to the standards of excellence in the field of laboratory medicine.

SURVEY PROGRAMS (PROFICIENCY TESTING FOR LABORATORIES)

Ideally all laboratories throughout the nation should report the same test results when they analyze the same specimens. This goal would seem paramount, particularly in our highly mobile society. Only if laboratory results are consistent can physicians throughout our nation exchange information on patients and be confident of its accuracy and applicability. While it may not be possible to achieve complete agreement due to technical limitations, there must be sufficient agreement to assure that significant changes in the medical status of a patient can be identified when possible with certainty and not be observed by analytic differences in test results between one laboratory and another.

One of the most significant laboratory improvement programs conducted by the College to meet the requirement of having laboratory test results agree is the CAP Survey Program. CAP Surveys (Interlaboratory Comparison Programs) are proficiency testing systems that define today's "state of the art." These

professionally developed and professionally managed Surveys are designed to monitor a laboratory's test results by comparing these results with the national mean, and results of reference laboratories and/or selected referee laboratories. Presently there are more than 9,000 laboratories participating in this interlaboratory comparison. This figure includes both hospital and independent laboratories, plus 850 physicians' office laboratories.

This program is the largest in the world by a substantial margin and is the most comprehensive as well. It is used by a majority of the clinical laboratories in the United States and by more than 400 laboratories in other countries.

Many of the laboratories participating in the CAP Survey Program are Federal government installations. At the present time the College is providing, under contract proficiency testing programs for:

1. Veterans Administration laboratories	193
2. Air Force laboratories	121
3. Navy laboratories (1976 figure)	35
4. Army laboratories	95

In addition, to meet the requirements for Medicare and/or state licensure, 44 state agencies have accepted participation in the CAP Survey Program as proof of meeting Federal requirements for participation in inter-laboratory testing.

Internationally, the College Survey Programs have been accepted by Japan, Australia, New Zealand, and the Canadian provinces of Saskatchewan, Alberta, and British Columbia for proficiency testing requirements.

The Commission on World Standards of the World Association and the Societies of Pathology are using College Survey data as a springboard for establishing standards on an international level.

The principle underlying the operation of the College Survey Program is simple. A series of specimens is mailed out to a large number of individual laboratories. These laboratories are asked to analyze the specimens for a variety of substances. The results of these analyses are reported to the College's Computer Center where the results provided by all the laboratories are compared. An evaluation report is then compiled with the aid of a computer for each individual participant.

The evaluation report permits each participant to compare the test results reported by his laboratory with the results obtained by the other participating laboratories.

When a laboratory uses the College program in lieu of participation in a State or Federal program, a copy of the laboratory results is mailed to the appropriate agency.

To the laboratory director, any discrepancies between the results his laboratory reported and the results that other laboratories reported serve as an immediate and vivid signal that something may be amiss. In a methodical and logical fashion, each factor involved in performing the particular test—human, mechanical, chemical and procedural—can be examined and verified until the factor, or factors, that caused the discrepancy are discovered and corrected if appropriate.

During 1976, the program mailed out 900,000 specimens to participants. The number of analyses that each participant performed on each specimen varied from one to as many as 21. These analyses provided 3 million individual test results that were handled through the CAP Computer Center.

A program of this size is possible only with sophisticated manufacturing techniques that can assure the quality of the specimens and equally sophisticated computer techniques that can handle the massive amounts of data involved.

A professional program as extensive as the College's offers many advantages and provides a new dimension in both monitoring and improving the quality of laboratory work in the United States. Its size assures that each participant is able to compare his results on a continuing basis with the results of 9,000 laboratories in the United States. It also provides a continual appraisal of the norms of performance of both the individual laboratories and of the various techniques, methods and commercial products that are used by participants in the testing process.

While the CAP Survey Programs are directed primarily toward the individual participant, they also are used by many governmental regulatory agencies. There are several ways in which the regulatory agencies use the program but they all are based on the same underlying principle. The same results that laboratory directors use to check the quality of their laboratories' work also are used by these agencies to determine whether the laboratories are operating at the desired level of performance.

Most states use the various programs for completing some or all of their requirements for monitoring of laboratories. In California, all laboratories are required to participate in either the College program or in one of the other accepted voluntary programs. Individual CAP Survey reports and summaries of the results reported by California participants also are reported to the California Department of Health, which maintains its own computer records on the performance of each laboratory. Similar CAP reports are sent to all other states, as well as to some agencies of the Federal government.

Participation in College programs is recognized by virtually all agencies as acceptable for proficiency testing in interstate and intrastate commerce. To meet the needs of these various interested Federal and state agencies, the College distributed more than 250,000 evaluation reports in 1976.

The data from the CAP Survey Program discloses clear and unequivocal evidence of steady laboratory improvement during the past five years. This is particularly apparent in areas which provide numerical results, such as chemistry and hematology. In each of these areas there is evidence that the slope of improvement is leveling off and that laboratories may be approaching the present technical limits of analytical precision. These improvements have been thoroughly documented in published reports and material.

The Survey Programs offered by the College include:

Basic.—4,178 participants. This program is designed to evaluate a small hospital (under 100 beds) laboratory or a small independent laboratory. For laboratories of this size the Basic Program can be used for accreditation in the College's Inspection and Accreditation Program. This Basic Program meets the requirements for Medicare and most state licensure programs. It does not meet the equivalency requirements under the provisions of the Clinical Laboratory Improvement Act of 1967 for interstate licensure.

Comprehensive.—Microbiology, 1,707 participants; Chemistry, 2,769 participants; Hematology, 2,756 participants; and Blood Banking, 2,425 participants.

These programs are designed for the large hospital laboratory serving 100 or more beds and for the large, sophisticated independent laboratories. For laboratories of this size, the Comprehensive Chemistry, Hematology, Microbiology, and Blood Banking can be used for accreditation in the College's Inspection and Accreditation Program.

The Comprehensive Programs are also designed to meet or exceed the proficiency testing equivalence requirements under the provisions of the Clinical Laboratory Improvement Act of 1967 for interstate licensure in Chemistry, Hematology and Blood Banking.

Special.—Bacteriology, 755 participants; Mycobacteriology, 276 participants; Mycology, 325 participants; Syphilis Serology, 1,020 participants; Parasitology, 528 participants; Diagnostic Immunology, 891 participants; Toxicology, 331 participants; and Urine Chemistry, 437 participants.

These programs are designed for evaluating the sophisticated microbiology laboratories and for use in teaching institutions and regular laboratories as a teaching mechanism for student technologists, technologists and residents. These Special Programs are also designed to meet the proficiency test requirements under the provisions of the Clinical Laboratory Improvement Act of 1967 for interstate licensure in the specific areas of Microbiology, Serology and Toxicology.

Pilot studies.—Instrumentation—Narrow band, 300 participants; Instrumentation—Wide band, 272 participants; Nuclear Medicine in-vitro, 1,057 participants; Nuclear Medicine radio-nuclide, 112 participants; Nuclear Medicine Phantom Imagery, 95 participants; and Hepatitis B Antigen, 425 participants.

These studies are new programs designed to assist in defining the "state of the art." They permit participants to evaluate their performance and provide the data necessary for developing standards in these specific areas of laboratory medicine. The studies were not designed to serve the function of proficiency testing.

It should be emphasized that radioisotopic techniques (Radiobioassay, Radio-Ligand Assay, In-Vitro Nuclear Medicine) are used in many phases of the clinical laboratory. Surveys of procedures requiring these techniques are included in the Comprehensive Chemistry program, the Special programs of Bacteriology, Diagnostic Immunology and Toxicology as well as the pilot programs of Nuclear Medicine in-vitro, radio-nuclide and Hepatitis-B Antigen.

Physicians evaluation program.—This program is designed specifically for the

physician's office laboratory. It is now being revised to incorporate the new Social Security regulations for Independent Laboratories under Medicare. The PEP Program has been approved by the states of Arizona, California and Maryland, which require proficiency testing for a physician's office laboratory. In 1976 there were 947 physician's office laboratories in this program.

This then is a brief review of the College's Survey Program, a program of international scope and reputation and acknowledged to be a significant factor in our never-ending educational efforts to improve the operation of clinical laboratories whatever their size and wherever they may be located.

CAP QUALITY ASSURANCE SERVICE

The College's Quality Assurance Service (QAS) is a computerized system for recording, analyzing, managing and documenting the daily internal quality control programs of medical laboratories. It is based on repetitive daily analyses in the laboratory over an extended period of time of a portion of a large sample pool. These control results are analyzed and plotted through the use of CAP's sophisticated computer programs which allow the laboratory to evaluate its results and to establish comparative data for internal quality control. Many state and regional groups have used the opportunity provided by QAS to combine the benefits of internal quality control with large group comparative data similar to that provided by the Survey.

QAS meets quality control criteria for voluntary and regulatory inspection agencies. In addition, QAS meets the requirements for documentation of daily quality control under these agencies.

Currently there are approximately 1,100 laboratories reporting daily results on 50,000 tests in this program.

APPENDIX B

Urine Screens in Monitoring Methadone Programs

To the Editor.

The recent special communication by Gottheil, Caddy and Austin entitled "Fallibility of Urine Drug Screens in Monitoring Methadone Program" (236): 1035, 1976) presents a number of points that deserve serious comment. In general, it appears that the investigators were not completly informed concerning the operation of urine drug testing programs and the agencies that regulate this clinical laboratory activity. This letter is intended to clarify and augment the data presented in their article.

The first item that requires elucidation relates to government proficiency testing and regulation of laboratories offering urine drug analysis services. Although it is true that the Federal Center for Disease Control (CDC) proficiency testing program has no provisions for preventing laboratories that perform unsatisfactorily in proficiency testing from conducting these analyses, the authors do not mention, and are perhaps unaware, that many state health departments also conduct proficiency testing in their respective jurisdictions and use such evaluations to determine which laboratories will be licensed or approved to perform these analyses. Connecticut, New Jersey, New York, Pennsylvania, and a few other states have all had programs to test and regulate laboratories involved in urine drug testing for several years. In Pennsylvania, our Bureau of the State Health Department has issued approvals to such laboratories since 1972 and has permitted only those laboratory facilities that perform satisfactorily in proficiency evaluations to offer drug analysis services. This program has resulted in a number of unacceptable laboratories being refused permits to perform urine drug analyses or having their approvals revoked for failure to demonstrate satisfactory capability. Subsequent training and consultation with such laboratories have resulted in obvious improvement.

It was also stated that acceptable proficiency testing scores are no guarantee that routine, day-to-day analytical work will be of the same quality. This statement is also true. Proficiency testing, at best, can only determine if a laboratory is adequately equipped and staffed to perform a particular determination reliably under optimal conditions. There is no doubt that proficiency-testing samples receive more attention than routine specimens. Indeed, this has been the basis for prohibiting laboratories that score below acceptable levels in evaluations from offering these services. The reasoning has been that a facility that fails to

accurately analyze test samples which receive special treatment will certainly be incapable of reliably processing routine specimens. The real problem in a regulatory program is not the obviously incompetent laboratory which is easily prevented from offering services, or the proficient facility which is easily identified, but the marginal laboratory whose test scores do not inspire confidence, yet are not low enough to warrant revocation of approval. Regulatory agencies do not have the prerogative of forbidding persons they suspect are inept from performing a specific analysis unless then can conclusively establish such a finding on an objective basis, such as by proficiency testing. In this regard, those seeking to obtain laboratory services should require prospective service providers to inform them of their scores in proficiency tests and should only contract with those facilities that have a record of consistently excellent performance. The only other guideline for clinics and physicians seeking reliable laboratory services is to check the reputations and credentials of the personnel of those facilities under consideration for contracts. In most instances, laboratories whose directors and personnel have established reputations for excellent in clinical toxicology provide the most dependable services. All too often the only criterion applied to the selection of a laboratory is cost of services, and this has frequently proved to be a tragic mistake. In situations where competitive bidding for toxicologic laboratory services is the policy, it may be difficult or impossible to obtain suitable analytical services unless other requirements are imposed.

The major portion of the remaining sections of the article by Gottheil et al. is concerned with a discussion of the use of "blind" testing and the interpretation of data they obtained from such tests. The authors point out that two laboratories with consistently outstanding CDC proficiency scores were selected for their study and that the laboratory that was not aware that the evaluation was in progress scored substantially lower, especially with respect to false-positive responses, than the other facility (which was informed). They imply that "blind" type evaluations give a more accurate appraisal of how a laboratory performs on a routine basis and advocate its use in proficiency testing. Indeed, this is probably true. However, the question of whether the use of "blind" testing to evaluate laboratories for licensure purposes is legally permissible is not addressed in the article. In Pennsylvania, this kind of testing has been considered and has been discussed with legal counsel. The prevailing opinion is that such procedures may constitute a form of entrapment and are therefore best avoided when evaluating laboratory performance. It appears that the legality of "blind" testing has not been adequately studied and that precedent-setting legal decisions are not available to assist in reaching a decision about this matter. Until the issue of "blind" testing is adequately reviewed and found to be legally appropriate, it is doubtful if any government testing agency will adopt such a practice. Another form of testing which is legally incontrovertible and approaches "blind testing" in effectiveness is on-site proficiency testing. This involves the employment of laboratory examiners who deliver test specimens to laboratories under evaluation and observe the technical personnel of those facilities while they analyze the samples. This approach, although it does not prevent test samples from receiving special attention, at least permits the testing agency to know what non-routine methods were used. This method is used by the Pennsylvania Department of Health to test laboratories that apply for urine drug testing approval and to reevaluate facilities that have had their approval suspended and are seeking reinstatement in the program.

Gottheil and colleagues state their conclusions that urine drug screening is inaccurate and is therefore misleading to the clinician and often detrimental to the patient. They further propose to remedy this situation by discontinuing urine testing and employ more personnel in treatment and counseling. To opt for such drastic changes would be more detrimental than helpful. As these authors state, the results of urine screening are frequently the only objective measures that clinicians have to evaluate the extent of a patient's drug abuse involvement. Rather than discard this information, physicians would be better advised to use this data with a realization of its limitations. It must be understood that a urine drug screen is qualitative, somewhat cursory, examination of a patient's urine for relatively high concentrations of certain substances. Such testing is a compromise. High sensitivity and selectivity are sacrificed in favor of low cost and rapidity of analysis. The technique of analysis is usually thing-layered chromatography and does not represent the most reliable or thorough method for determining urine drug content. Urine drug screens provide only an indication of

what may be the actual situation. If the physician has reason to doubt the results or if the patient disputes the findings, the physician should request a second analysis or should ask for confirmatory tests using more reliable techniques. Confirmatory testing is costly and may be time-consuming, but it is necessary if definitive laboratory results are required.

In summary, urine drug screening may often be helpful in evaluating the status of persons undergoing treatment for drug-related disorders. However, this information must be used properly and caution must be exercised in the interpretation of the results of such tests.

Mr. ROSTENKOWSKI. Thank you very much. Mr. Duncan?

Mr. DUNCAN. Thank you, Mr. Chairman.

I gather you are in opposition to universal blind proficiency testing of laboratories, but you also indicate that you would support blind testing in case of fraud. Is that correct?

Dr. HUTCHENS. That is correct. We do believe there are major problems in any universal, wide application, but it could be managed in specific situations.

Mr. DUNCAN. Since the language of this bill is permissive and is not mandatory with respect to blind proficiency testing, do you think we could take care of your suggestion by including language in the committee report that would express our understanding that we expect the testing should be done on a selective basis?

Dr. HUTCHENS. Yes.

Mr. DUNCAN. On the competitive bidding, you expressed a concern about that. Is that correct?

Dr. HUTCHENS. Yes.

Mr. DUNCAN. Would you say that most laboratories in urban centers are equipped to enter bids, to engage in competitive bidding?

Dr. HUTCHENS. I think it would be very difficult to evaluate that, and that is one of the bases for our concern. In some previous testimony this morning, it has been indicated that there are many components that go into charges for laboratory services, and our information is that one might, in competitive bidding, accept a bid for only a small part of minimal total services that would not really provide reimbursement for all of the activities that go on.

Mr. DUNCAN. Is that the feeling of most professionals in the field?

Dr. HUTCHENS. That is our position, and——

Mr. DUNCAN. Some States have tried competitive bidding, haven't they?

Dr. HUTCHENS. I personally am unaware of any trial on that. I just don't have any detail on actual trials.

Mr. DUNCAN. I thought it had been tried. Would you anticipate the low bidders would send things out of the State for testing and you wouldn't have the close relationship between the physician and the laboratory?

Dr. HUTCHENS. We believe that is one of the possible dangers, that it would remove the testing to a remote site, and would not provide the feedback not only of results, of judgments and results that might relate to the interpretation of that particular test.

Mr. DUNCAN. The pulmonary and cardiac, or so-called highly specialized laboratories, now are not included on the same basis as most other laboratories with respect to application of the national standards. You say they should be included?

Dr. HUTCHENS. Our belief is that all laboratory procedures performed in the United States should meet the same high standards. As I indicated in our oral testimony and is expanded in our written testimony, we don't see any justification for having a particular procedure, say a blood gas procedure, when it is in a laboratory determining cardiac function to be exempt, and to have the same procedure, when it is performed in a central laboratory, to be covered.

Mr. DUNCAN. They are separate now in some of the States?

Dr. HUTCHENS. Well, are you speaking of the situation in individual hospitals?

Mr. DUNCAN. Yes, sir.

Dr. HUTCHENS. In the individual hospitals, there is a whole spectrum of arrangements. In my hospital and in my clinical laboratory, blood gas determinations that are done are done in a section of our laboratory that, for convenience, is in the intensive care unit.

However, we are responsible for and operate and staff and apply all the quality control programs and personnel standards for that activity. So in that case those procedures, blood gas procedures, are done under the same controls and procedures as are done in our central lab for other purposes.

In other institutions, these are separated administratively from the central lab, and there sometimes are or are not quality control programs, and the qualifications of the personnel are not always standardized or controlled.

Mr. DUNCAN. Doctor, what State do you practice in?

Dr. HUTCHENS. Oregon.

Mr. DUNCAN. Do you have a State regulatory program?

Dr. HUTCHENS. We have a State licensing law.

Mr. DUNCAN. Do you believe it is good?

Dr. HUTCHENS. I believe it has contributed to the raising of laboratory standards. I believe there have been problems in implementation because of shortages of resources to support the program.

Mr. DUNCAN. Do you think all States have a licensing law?

Dr. HUTCHENS. I am not certain at this time how many States have a licensing law.

Mr. DUNCAN. Thank you. Thank you, Mr. Chairman.

Mr. ROSTENKOWSKI. Mr. Gradison?

Mr. GRADISON. I would like to pick up on that.

Do you have any idea how large a staff is at work at the State level, statewide in Oregon, supervising and inspecting the clinical laboratories in your State?

Dr. HUTCHENS. It is a very small staff. I don't have the exact details, but my impression on the basis of communications with them and on the basis of their visits to our laboratory once a year, is that it is not more than two people who actually go out in the field and inspect, and it appears that most of the burden of evaluation of that, plus monitoring of Federal programs relating to the laboratory field is confined to about that number, and they indicate that they really don't have the staff to do the job they would wish to do.

Mr. GRADISON. How would you feel about a Federal law that was written so that it would exempt the States from the standards set down by HEW, rather then have any Federal inspection in those States?

Dr. HUTCHENS. We believe in provisions for equivalency, both for State-level programs and the voluntary programs, such as the College of American Pathologists' proficiency program.

We are concerned, however, about States developing, even though they are equivalent to the standards of the Federal program, developing many diverse programs that would make it difficult to interpret the results and also make it difficult, say, for a nationwide voluntary program to become equivalent in each one of those States.

Mr. GRADISON. Thank you, Mr. Chairman.

Mr. ROSTENKOWSKI. Thank you. Thank you, gentlemen.

Mr. DUNCAN. Mr. Chairman, I am through. I would like unanimous consent to a letter in the record from Dr. Daniel F. Beals, a pathologist from Knoxville, Tenn.

Mr. ROSTENKOWSKI. Without objection, so ordered.

[The letter from Dr. Beals follows:]

KNOXVILLE, TENN., *April 21, 1978.*

Hon. JOHN J. DUNCAN,
Rayburn House Office Building,
Washington, D.C.

DEAR JOHN: H.R. 10909 as ordered reported by the House Commerce Committee contains three features which I feel will represent serious problems in implementation and will be counterproductive to efficient patient care through laboratory medicine. These are as follows:

1. "Exemption of highly specialized laboratories." This proposes to exempt pulmonary function laboratories and "cardiac" testing laboratories. As you know in Tennessee we have a model laboratory licensure and control act which is functioning well after ten years of operation. It has been the position of the Licensure Service and of the Technical Advisory Committee of which I am a member to include the pulmonary function laboratories in future laboratory regulations. Our investigation indicates that these are procedures which fall under the definition of laboratory testing in every sense of the word in that they require technicians to test patients with the use of technological equipment with the production of results which will be used by a physician for the purpose of diagnosis and/or treatment of a human patient. These procedures do not differ significantly from the broad range of activities generally defined as laboratory testing. A similar statement can be made regarding the cardiac function laboratories. I feel that it would be inappropriate to exclude these specialty laboratories from the national legislation. This would undoubedly set a precedent which would invite other groups testing a small segment of the laboratory spectrum to insist upon similar exclusion and indeed avoidance of control under the CLIA 78 Legislation. There is also a definite problem that entrepenuers sometimes from out of state seek to establish highly lucrative and essentially unsupervised pulmonary function and other testing laboratories in smaller communities without the necessity of meeting the standard minimum criteria required for legitimate clinical laboratories. In short, I feel there can be no reason for exclusion of these groups. If other laboratory tests must be done by well trained and well supervised technicians using properly controlled equipment I see absolutely no reason why the cardiac and pulmonary function areas should not meet the same standards.

2. The "onsight" and "blind" proficiency testing feature ("Maguire Amendment") represents an unworkable and ineffective concept. We have now had extensive experience with a very well founded and carefully controlled laboratory proficiency survey as furnished to participating laboratories by The College of American Pathologists. I am aware of the massive technological and management complexity of furnishing this type of program and assuring that the material sent out for testing indeed represents a valid set of materials. These problems are caused by the difficulties in preserving specimens and maintaining a creditable and valid assay of the material which is itself sent out as "the test". Those who would add on to this program the concept of "onsight" and "blind" testing have taken the somewhat ridiculous view that the CAP program is somehow failing to effect quality survey simply because it can be identified as

survey material. We find in practice that this is simply not a problem. The addition of these proposed formats of testing are unnecessary and would be extremely expensive and difficult to implement in a fair and professional manner. One aspect of this which I personally would find inappropriate is the concept of the blind specimen. This would require that the Pathologist submit to his personnel a specimen using a patient's name and disguised in the usual container used in his laboratory. This would require the Government and the Pathologist to enter into a subterfuge which many, including myself, would find unacceptable. Someone would have to lie to the personnel about such specimens, and I personally will not take that responsibility. I find it ironic that the present wording of this Legislation proposes that a Government Agency itself engage in such a deceptive practice. Completely aside from this is the practical situation. This type of testing is simply not necessary.

3. Competitive Bidding. There is a provision in the present language which authorizes States to seek competitive bids for Laboratory services under the Medicaid program. I realize that this is a practice which has been tried from time to time. Very recently when this was instituted in the State wide Cytology Screening Program by the State of Tennessee it had the direct result of disintegrating a carefully constructed voluntary state wide network of Clinicians and Cytopathologists. It is widely opposed by the professionals in the field because it is our feeling that much lower quality service is generated when the material is let out to bid and this is subsequently sent out of the State to a large distant commercial operation. This completely blocks the possibility of a close communication between primary physician, patient, and cytopathologist. It is also our experience that large commercial laboratories capable of submitting the lowest bid do not necessarily furnish better quality work. In fact, those of us who operate laboratories regularly have found that increasing size creates increasing problems of quality control, management and communication.

I want to thank you for your conscientious representation of the best interests of Tennesseans. I would not trouble you with the details above were it not for my feeling that these three concepts represent serious detractions from the CLIA Legislation which otherwise takes an approach which we have recognized as acceptable in our own state.

Sincerely yours,

DANIEL F. BEALS, M.D.

Mr. ROSTENKOWSKI. Mr. Young and Mr. Weissman. Welcome to the committee.

STATEMENT OF WILLIAM YOUNG, COORDINATING COUNCIL FOR CLINICAL LABORATORY TECHNOLOGY, ACCOMPANIED BY DENNIS W. WEISSMAN, DIRECTOR, OFFICE OF GOVERNMENT RELATIONS, AMERICAN SOCIETY FOR MEDICAL TECHNOLOGY

Mr. YOUNG. Mr. Chairman and members of the Subcommittee on Health, I am Mr. William Young, and I appear before you today to testify on the Clinical Laboratory Improvement Act, H.R. 10909, on behalf of the Coordinating Council for Clinical Laboratory Technology (CCCLT).

With me today is Dennis Weissman, director, office of government relations, American Society for Medical Technology.

The council is composed of the following three professional laboratory organizations: The American Society for Medical Technology (ASMT), American Medical Technologists (AMT), and the International Society for Clinical Laboratory Technology (ISCLT). Combined, the member organizations of the council represent nearly 50,000 nonphysician clinical laboratory personnel including clinical laboratory administrators, supervisors, educators, technologists, technicians and a variety of laboratory specialists.

It is a pleasure to appear before you this morning, Mr. Chairman, because both our individual organizations and the council support the passage of H.R. 10909, with some suggested changes which I will summarize this morning. This legislation is needed in our collective opinion, and throughout its course in the Congress each of our organizations has supported the major thrust behind the legislation. In particular, Mr. Chairman, we find title II dealing with the social security amendments, study and report to be generally acceptable and so lend our support.

We do feel, however, Mr. Chairman, that there are several provisions contained in H.R. 10909 which should be modified.

In this regard, the council is most concerned with the current language in the bill pertaining to qualifications for personnel below the technologist level.

Although the roles of clinical laboratory personnel may vary depending upon the level and type of training, all laboratory practitioners, including technicians, contribute to the performance of scientific analyses to provide the medical community with data upon which to base decisions concerning the diagnosis and treatment of disease. The absence of accurate data greatly diminishes the physician's ability to deal with the many medical decisions necessitated in his mission to provide quality care to his patients. This important principle has been firmly established under the medicare program for the last decade. Under its conditions of coverage of services of independent laboratories, medicare adopted and has in force qualification standards for all laboratory personnel including the technician level.

As reported out by the Interstate and Foreign Commerce Committee, H.R. 10909 proposes to eliminate qualification standards for laboratory technicians and substitute in their place the requirement that supervisory personnel, through periodic practical examinations, evaluate the proficiency of technicians employed in laboratories.

Without belaboring the point that such evaluations will largely be based upon differing interpretations made by individuals who may not always be able to apply their honest judgment freely, it is clear that the current language contained in H.R. 10909 does not provide sufficient guarantees to assure the quality of technician work.

This legislation fails to recognize the fact that many qualified technician personnel are being trained in numerous institutions accredited by agencies recognized by the U.S. Office of Education.

Since prior education and experience is not recognized at the technician level as a basis for qualification under the proposed bill, the incentive for individuals to obtain an appropriate training background would be markedly decreased. This situation is both unjust and inequitable to the many qualified technicians that would be affected by this provision. The real losers unfortunately would be the American public who are not being given sufficient guarantees regarding the competency of technician personnel performing diagnostic laboratory tests.

Mr. Chairman, we are not suggesting that the only individuals permitted to work as laboratory technicians should be those who have completed a structured training program. What we are saying, however, is let's recognize those individuals who are properly trained like we do throughout the rest of the health-care system and provide

alternative qualification routes such as proficiency or practical examinations to assure the competency for other personnel who may wish to qualify. The Senate-passed version of CLIA requires the Secretary to promulgate appropriate standards for all personnel, and we urge the subcommittee to accept these provisions.

In addition, Mr. Chairman, in line with recommendations made by the Department of Health, Education, and Welfare, the Commerce Committee deleted from the proposed legislation an Office of Clinical Laboratories, an HEW advisory committee, and the authority to regulate blood banks where they form an integral component of the overall clinical laboratory. We strongly believe the deletion of these provisions from H.R. 10909 seriously compromises several important objectives which must be realized in the legislation. These include the need for better policy coordination of HEW's laboratory-related responsibilities, full private sector advisory participation in the implementation of the bill's various provisions, and finally, alleviation of the duplicative and overlapping administration between different components of the clinical laboratory located within the same facility.

Since these provisions are integral to resolving existing problems in the current Federal regulatory laboratory program and are already included within the Senate-passed bill, S. 705, we respectfully recommend that they be reincorporated during your committee's deliberations on this important measure.

Another serious problem we have identified in H.R. 10909 is the lack of appropriated funds for the examinations mandated by the legislation which are required to be completed within 1 year from the date of enactment. This provision as currently incorporated within the legislation is highly impractical for two basic reasons: The development of such examinations would take a minimum of 2 years to complete and would require anywhere from $5 to $7 million to develop.

In light of these facts, we jointly urge that H.R. 10909 be further amended to provide for a more appropriate time frame for the examination development—minimum of 2 years—along with specific appropriations, $5 to $7 million, allocated for such development.

We hope that the subcommittee will act favorably on this legislation and that our comments will be helpful in that deliberation.

We shall be happy to respond to any questions you or other members of the committee may have at this time, Mr. Chairman.

Mr. Rostenkowski. Thank you, Mr. Young.

Mr. Corman. Mr. Chairman, I just want to ask one thing.

Is there any problem with conflicts of interest with doctor-owned laboratories that you know of? There was a problem some years ago in California, and as far as I know, California solved it.

Mr. Weissman. I think there have been problems with some physician-owned laboratories when that same physician is also director of a hospital clinical laboratory. When a physician has an independent practice outside the hospital as well as responsibility for a hospital laboratory, a possible conflict of interest may exist in that he can direct a certain amount of testing done for patients in his hospital laboratory to his independent laboratory outside of the hospital.

Also, in terms of physicians who own certain outside companies which may supply reagents, et cetera, to a hospital laboratory. If that physician is the director of a hospital laboratory he can then direct

that hospital to purchase supplies from his own corporation, then there could perhaps be some conflicts of interest in those situations, and I think there have been reports of that around the country.

Mr. CORMAN. There is no prohibition as far as the Federal Government is concerned in that respect, is there?

Mr. WEISSMAN. No; I don't believe so.

Mr. YOUNG. No.

Mr. ROSTENKOWSKI. Mr. Duncan?

Mr. DUNCAN. No questions.

Mr. ROSTENKOWSKI. Mr. Gradison?

Mr. GRADISON. No questions.

Mr. ROSTENKOWSKI. Hon. James R. Jones, a Member of Congress from Oklahoma.

Welcome to the Subcommittee on Health, Mr. Jones.

STATEMENT OF HON. JAMES R. JONES, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OKLAHOMA

Mr. JONES. Thank you, Mr. Chairman, and members of the subcommittee, for giving me this opportunity.

I would like to summarize my comments and ask that the full text be included in the record.

Mr. ROSTENKOWSKI. Without objection, so ordered.

Mr. JONES. Mr. Chairman, I appreciated working with this subcommittee on the self-dialysis and the renal disease program. What I have today are specific amendments to the Clinical Laboratory Standards Act which may actually fall within the jurisdiction of the Commerce Committee, but these recommendations came to me after Commerce had completed its markup. I will forward my comments to Chairman Staggers and Chairman Rogers additionally.

The first of my three points pertains to who is to be covered by this particular act.

In my State of Oklahoma we have had a very aggressive program of setting standards and cutting down error rates. Laboratories in my State, I am told, meet the national standards and exceed them as provided in this legislation; but under this legislation, all the reporting requirements will increase laboratory costs in rural areas by 20 to 30 percent.

So, one of the amendments that is recommended in my testimony is that where those States, or those labs, are meeting the tests of performance in error rates, they should not be covered by all the reporting requirements under this act.

The second part of my testimony deals with the concern about the requirement for separate licensing of laboratory facilities. There are situations in my State where the same centrally operated laboratory will have two different physical facilities.

According to the legislation, as I read it, and as the people in my State read it, this would require two separate expensive licensings. The second part of the testimony offers specific language to amend the act to require only one license where there is a centrally operated laboratory, even though it may be in two different physical facilities.

The third part of the recommendation made in my testimony deals with the provisions for competitive bidding for laboratory services.

Medical professionals from my State have urged that quality be considered an important element of the bidding process and urge adoption of a provision that competitive bidding means bidding for the same level of laboratory service for each laboratory analysis rather than simply bidding for each type of test.

The language is in my extended testimony.

I appreciate this opportunity to present it to the subcommittee.

[The prepared statement follows:]

STATEMENT OF HON. JAMES A. JONES, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OKLAHOMA

My testimony this morning focuses on three issues which I feel deserve more attention as the Subcommittee considers the Clinical Laboratory Standards Act.

My first area of concern is application of new clinical laboratory standards in States which have already achieved a low error rate and have implemented monitoring systems which give every indication of perpetuating low error rates and high quality in laboratories.

My home State, Oklahoma, has already demonstrated ability to exceed the level of performance toward which the Clinical Laboratory Improvement Act is directed. The new standards will raise laboratory costs in rural areas by 20 to 40 percent, according to estimates given to me by laboratory representatives in my State. My recognition that some States have already achieved quality laboratory standards leads me to pose the following question: Why should a law that will increase medical costs be implemented if the problem it is designed to solve does not exist?

I propose insertion of language in the bill that will encourage States to continue their own initiatives to upgrade laboratory standards. If States fail in this regard, then they would be required to comply with the other provisions of H.R. 10909.

My second area of concern involves the requirement for separate licensure of laboratory facilities. In many cases, laboratory stations are staffed, supervised, and operated as part of a central laboratory. Even expansion of one laboratory to a second building requires a second license. I urge amendment of H.R. 10909 to allow for one license to any laboratory using a separate physical location but which has central control, management, and physician supervision of the activities of these separate locations.

The final issue which I wish to raise involves the Act's provisions for competitive bidding for laboratory services. Medical professionals from my State have urged that quality be considered an important element of the bidding process. I urge adoption of a provision that competitive bidding means bidding for the same level, or quality, of laboratory service for each laboratory analysis, rather than simply bidding for each type of test.

I have more detailed testimony on this subject which I wish to submit to the Subcommittee. I am also sharing this more detailed testimony with Chairman Rogers and Chairman Staggers.

ISSUES

For the past ten years the clinical laboratories in metropolitan and rural Oklahoma have undertaken an aggressive joint program to upgrade the quality of clinical laboratories. An extensive system of quality control, personnel training and urban-rural cooperation have created a system of laboratories whose low error rate is among the best in the Nation. The Oklahoma physicians want to continue this system if at all possible.

More recently the State Medical Association, State Hospital Association and the Oklahoma Utilization Review Systems (OURS) have developed a very effective monitoring approach for "peer review" that has evolved into an important innovation in medical and hospital cost control throughout the State. The potential for using this system in all medical areas is promising, particularly for monitoring the quality of clinical laboratory performance in concert with the present clinical laboratory quality control efforts in the State.

A preliminary review of the cost of implementing the Clinical Laboratory Improvement Act standards in rural laboratories, if these new standards are close to the present interstate clinical laboratory standards, is estimated at

20–40 percent. This cost increase would occur despite the fact that Oklahoma clinical laboratories now exceed the level of performance sought by the Clinical Laboratory Improvement Act. Why should a law that will increase medical costs be implemented if the problem it is designed to solve does not exist?

A better answer would be to allow a State who now far exceeds the average performance of laboratories to establish its own clinical laboratory monitoring system if it is able to maintain its present low clinical laboratory error rate. If the low error rate is not maintained then the State should have to comply with the other provisions of HR 10909.

Attached is language which would provide for a State to utilize this alternative. In effect, it places the emphasis in HR 10909 on performance, rather than the implementation of an elaborate standard setting, licensing and reporting process. If a State illustrates that it does not have the problem that CLIA is designed to solve then it can continue to upgrade its present program until a high error-rate problem arises.

HR 10909 pg. 19 line 18 insert the following paragraph:

(1) can illustrate that the error rate in its clinical laboratories is at least 1% below the average error rate among clinical laboratories in the United States and that there is an established program within that State to monitor and evaluate the performance of all clinical laboratories to determine whether that low rate of error is maintained.

(Old line 18.)

(2) has adopted (1) standards

ISSUE

The definition of a Laboratory in the Clinical Laboratory Improvement Act causes a problem for some laboratories in Oklahoma. HR 10909 Section 370(1)(B) Definitions define a "laboratory" and "clinical Laboratory" to include all facilities used "for the collection, processing or transmission of said material for such purposes". The law goes on to state that each of these facilities must be separately licensed.

The problem in Oklahoma is that some laboratories have up to five collection stations which are staffed, supervised and operated as part of a central lab. In another case, a laboratory has expanded to two buildings—one across the street from the other. The law now requires a separate license (up to $500) and reporting system for each of these laboratories. Everyone agrees this is not the intent of the legislation and that the Secretary will make that clear in the regulations. However, there is some confusion and we would rather have this covered in the legislation.

RECOMMENDATION

Perhaps HR 10909 could be amended to allow for one license to any laboratory using separate physical location but which has central control, management and physician supervision of the activities of these separate locations. The wording would be:

(C) A group of facilities with one general geographic area under central management, supervision and physician control can constitute one facility for the purposes of this Act.

ISSUES

The Clinical Laboratory Improvement Act provides for a process of competitive bidding for laboratory services. Many Oklahoma doctors are concerned that this type of competitive bidding process developed through this legislation might not be so competitive.

The problem is that there is a "quality" element that must be part of any bidding process. For example, the type of lab service desired, particularly in rural areas of Oklahoma, may include daily pick-up, twenty-four hour pathologist consultation and follow-up testing. This type of service has proven to be the most cost-effective and reliable for small hospitals. On the other hand, mailing in samples to a central lab and receiving the reports two weeks later is satisfactory for some other types of tests. In other words the specifications of the type of services required to make the testing most useful is very important to Doctors and Hospitals. Thus, there is a need to include within the bill a provision that competitive bidding also means bidding for the same level of laboratory service for each laboratory analysis rather than simply that each type of test must be bid on its own.

RECOMMENDATION

(Added to HR 10909 pg. 47 line 21.)
"and the specifications fo reach service bid upon must provide for services of excellent quality."

Mr. ROSTENKOWSKI. Thank you, Mr. Jones.

You are aware, of course, that there is a jurisdictional difference here in many of the areas that you have addressed yourself to that will have to be taken up by Mr. Rogers in the Interstate and Foreign Commerce Committee. We expect to work closely with him, and any recommendations you make certainly will be considered by this subcommittee.

Mr. JONES. I know this subcommittee is very persuasive and has great leadership, and that is why——

[Laughter.]

Mr. ROSTENKOWSKI. Mr. Corman, do you want to add anything to Mr. Jones' observations?

Mr. CORMAN. The quality of the leadership of this committee is reflected by the quality of the witnesses.

Thank you, Jim.

Mr. ROSTENKOWSKI. Mr. Duncan?

Mr. DUNCAN. In other words, if the State has a good program, you don't think it should be covered under this act? Is that it?

Mr. JONES. We certainly don't, particularly if it is going to increase the cost of health care.

Mr. DUNCAN. If it isn't broke, don't fix it?

Mr. JONES. That is right.

Mr. ROSTENKOWSKI. Mr. Gradison?

Mr. GRADISON. I would like to thank the gentleman for his comments and also point out that there seems to be inconsistency that the whole program of inspection can be carried out with 27 people, or some such number, and the testimony from one State, Oregon, that they have two people doing the job and not doing all that needs doing in that State. If you put that two people on a nationwide basis, you are talking about at least a couple hundred. Oregon has about 2.5 million people or thereabouts.

Thank you.

Mr. ROSTENKOWSKI. Mr. Cotter?

Mr. COTTER. No questions, Mr. Chairman.

Mr. ROSTENKOWSKI. Senator Javits, welcome to the Subcommittee on Health.

Senator JAVITS. How do I get out?

Mr. ROSTENKOWSKI. You came in the back door.

STATEMENT OF HON. JACOB K. JAVITS, A U.S. SENATOR FROM THE STATE OF NEW YORK

Senator JAVITS. Good morning.

Mr. ROSTENKOWSKI. Welcome, Senator. We certainly hope your meetings earlier this morning were fruitful.

Senator JAVITS. We certainly tried.

Mr. ROSTENKOWSKI. We want to congratulate you on your leadership. We are certainly aware of all you have done, and we will cooperate with you to the fullest. We are glad you can join us this morning.

Senator JAVITS. You are gracious about setting this hearing, and I want you to know I come as a former Member of the House, with a full understanding on the House's position on matters on which the House and the Senate differ.

In order to save the committee's time, I ask unanimous consent that my statement be made part of the record, as if read.

Mr. ROSTENKOWSKI. Your entire statement will be put in the record.

Senator JAVITS. I will highlight the situation.

The fundamental point we agree on, that is, that it is inadequate to have a law that applies only to the commercial laboratory, less than a thousand, without recognizing the problems with which you are faced in your particular jurisdiction, which is medicare and medicaid, and we are faced in our jurisdiction, which is health care, with respect to testing.

Like so many things in our lives, and perhaps it goes to Mr. Gradison's point, this thing has just grown, "grown like Topsy," and we so far find it very difficult to find techniques which challenge the doctors.

The first question is: Why so many tests? Why, suddenly, do laboratory tests account for 10 percent of the health bill of the United States? Why is it routine when you walk in anywhere—a clinic, a hospital, or a doctor's office—to do a complete battery of tests.

My own opinion is that we will, in trying to do something about this in a sensible way—I have no desire to unnecessarily supervise anybody, or engage huge bureaucracies in the process—and I hope we can get a handle on this. One, we will know more about it; two, it will be more professionally handled; and three, and here I agree with the subcommittee, there will be a stern effort to see that the cost fits the service.

Where the service is not necessary, it is not paid for. That is the easiest way to discourage unnecessary testing.

Now, as to the position of the legislative committee which dealt with the health aspects, on the Interstate and Foreign Commerce Committee, there are some differences between the House and the Senate.

I would like to pledge to you, Mr. Chairman, and I have already discussed this with Paul Rogers, that we will meet with the utmost humility. Nobody's feet are "fixed in concrete," certainly not mine.

The House differs with us on some material things. For example, they want to be much less in the regulation phase respecting physicians. Really, they want it to apply only to group practice with five or more physicians. We will discuss it with them. I am not in any way overboard on that proposition.

It is claimed that the work that is done in single physicians' offices, which affects lives as much as anything else, requires some kind of supervisory activity. I think we have designed in the Senate a way in which to do that without badgering the physician. That is, all he has to do is to certify once a year under oath what he is doing and his qualifications. But I will listen with the greatest care in the effort to get together with the House.

There is some difference as to the level at which to qualify professional personnel. The House wants to limit it to above technicians. The hierarchy is apparently technician, technologist, and pathologist.

The whole point I wish to make is that my approach will not be rigid in any way, and I know that is true of our committee.

Now, as to your particular cares, I would welcome, Mr. Chairman, any additional lock that you want to put on the question of reimbursement and on the question of physician markups. There has been serious complaints about markups, kickbacks, and other frauds on the public. This is all public money and these funds have not been recovered. The Senate bill contains criminal penalties for such activities.

I am much too devoted to civil liberties to take criminal penalties lightly, but I do think there is a tremendous reaction against the inside deals which have been discovered as we investigated these matters.

Controlling the billing practices, that is, requiring the physician to account to whom he paid and what he paid, for the testing would get some control over fraud. But if you gentlemen desire to go further, we will certainly consider that with every sympathy, because we, like you, are dedicated to eliminating fraud and abuse as much as possible.

Last, on the matter of competitive bidding, which I just heard one witness testify to, we have a 1-year experiment in competitive bidding. We don't know how it will work. The House has a 3-year provision. Now again, should you decide to do something else about that, that is your department, as the Ways and Means Committee, because it is a medicaid reimbursement proposition.

We welcome any initiative or ideas that you have, and I know that that is characteristic of my committee, and I have no doubt of the House committee.

Finally, Mr. Chairman, I would like to say this, and I was much impressed with what Mr. Gradison said about the bureaucracy. I was a business lawyer long before I was a Congressman, let alone a Senator, and I am not one of those men who believes in spending $100 to save the last $200. The best run department stores and chainstores have leakage, to wit, stealing, and lots of other things. It is generally considered that 2 percent is a very acceptable record, and so I can assure you, Mr. Gradison, if it is up to me, I am not going to try to spend a lot of the public's money to reach the guy with the last $2. There is so much to do, and so much pruning that can be done that, as far as I am concerned, I want to get to the main points that have plagued the public.

Again, anything the committee wants to do on that, any limitations, I will welcome. This is an idea whose time has come. I am very hopeful that with intelligence and care that we will be able to extend this system so that it is more effective for the public.

Thank you, Mr. Chairman.

[The prepared statement follows:]

STATEMENT OF HON. JACOB K. JAVITS, A U.S. SENATOR FROM THE STATE OF NEW YORK

Mr. Chairman, first I would like to express my deep appreciation to you for the expeditious manner in which these hearings were arranged. As the author of the Clinical Laboratory Improvement Act (CLIA), I am very hopeful that the Ways and Means Committee will shortly clear the way for the passage of CLIA in the House of Representatives. I am especially concerned that the House should act on CLIA this year, since the Senate has already passed clinical laboratories legislation twice.

In 1976 the Senate first passed CLIA by a recorded vote of 64–11. Although a comparable version was reported from the House Interstate and Foreign Commerce Committee, unfortunately, due to a heavy legislative calendar at

the end of the session in a Presidential election year, the measure was not acted upon by the House of Representatives. The Senate, again passed the Clinical Laboratories Improvement Act on July 28 of last year.

My interest in this subject is of long standing. Thirteen years ago, in 1965, then Senator George Murphy of California and I introduced the first legislation to require interstate laboratories to comply with minimum safety and quality standards. Although that legislation, which became law in 1967, measurably improved the quality of interstate laboratory performance, it applied only to six percent—under a thousand—of all medical testing laboratories in the country.

Since then congressional hearings have revealed that almost half the States have no legislation with respect to professional standards in clinical laboratories and that the statutes of many of the remaining states are largely ineffective. Numerous studies have been offered which indicated variances in laboratory testing errors from seven to twenty-six percent. Further, in many areas the poor and unsuspecting are increasingly victims of fraud and abuse by a minority of unethical, "fast buck" medical practitioners in kickbacks, unnecessary tests and other nefarious practices.

This has compelled the development of this measure which extends and expands the existing program of mandatory licensure under appropriate conditions to all laboratories—the 14,000 independent and hospital based clinical laboratories and over 50,000 medical laboratories in physicians' offices—to ensure the quality testing standards are met and fraud and abuse prevented.

I think it is especially appropriate, therefore, that this Subcommittee will take a close look at the fraud and abuse provision that directly affect the Medicare program. Mr. Chairman, there is "larceny in the laboratory"—and it must be stopped! Consider the following:

1. Investigators of the Senate Committee on Aging found rampant fraud and abuse perpetrated by clinical laboratory firms. Findings from that Committee have established that as much as $1 out of every $5 in Medicare and Medicaid laboratory testing payments are fraudulent or at least questionable. The first and principal recommendation of the staff report prepared for the Special Committee on Aging is "(1) The Clinical Laboratory Improvement Act of 1976 should be enacted at the earliest possible opportunity."

2. Because "certain criminal elements are involved in the purchase of laboratories." there is a major fraud investigation in New York City by the U.S. Attorney's Office.

3. The Government Accounting Office—the investigatory arm of Congress—reports that its examinations in four states and the District of Columbia show physician markups of 151 percent in their billing to Medicare and Medicaid for patient laboratory work done in independent laboratory services.

4. Key laboratory personnel—medical technologists—testified to the need for employee protection provisions in the law so they can come forward freely to tell us in Congress the truth about the quality and accuracy of laboratory work; and the fraud and corruption in the medical laboratory business.

Furthermore, Senate hearings have revealed that, even beyond our strong concerns about fraud and abuse, there is the fundamental issue that many tests are inaccurate because of a lack of competent standards of clinical laboratory testing. For example, the Center for Disease Control (a U.S. government agency) estimated that nationwide 51 percent of all laboratory tests are in error. This amounts to almost two million test errors every day. To those who claim the quality of medical laboratory performance is not the problem it once was, I cite a July 22, 1976 HEW report in which a federal survey of approximately 200 independent Medicare laboratories revealed that 74 percent of the laboratories were found to have significant deficiencies.

The consequences of these deficiencies in terms of human suffering can be severe—when a patient dies because of a faulty blood type report, a child develops severe retardation from treatment based on an incorrect bilirubin test, or when cancer in a patient goes unnoticed—all because a laboratory test was incompletely conducted or read.

Let me call the Committee's attention to these actual case abstracts:

Schnelby v. *Baker*, 217 NW 2nd 708 (Iowa 1974), where a laboratory furnished wrong results on the bilirubin level because of an unreliable reagent solution—and thus an RH negative baby was not transfused, which resulted in a severely brain damaged infant.

Cornell v. *Clinical Laboratories*, Cal. Super, Ct, Los Angeles City. Docket No. NCC 3792, June 29, 1971, 25 Citation 163 (1971), where a patient suffered invasive cancer as a result of delay in diagnosing cancer, due to an erroneous laboratory test result from an inadequate Pap smear.

Kinel v. *Hycel Inc.*, Ill. Cty Cir. Ct, No. 70 L241 (Nov. 3, 1973), where a patient suffered irreversible brain damage, lapsed into a coma and died, when a physician prescribed the wrong medication (insulin for diabetes) based upon a faulty laboratory test finding of blood sugar level.

These problems are compounded by the bureaucratic problems attendant on federal responsibility for assuring the quality of laboratory activities—there are three different agencies responsible for administering the program—and the record demonstrates that one agency often does not know what the other is doing.

When I testified before the House Subcommittee on Health and the Environment last year, I was asked about the interagency laboratory agreement that allegedly negated the need for this legislation. I responded that I had little faith in its becoming meaningful. The accuracy of my response and the fact that we should not rely on it—given the long history of bureaucratic backbiting and infighting—was regrettably brought to public attention in a memo dated January 24, 1977. In it the Center for Disease Control, which is responsible for present interstate licensure of medical laboratories under the CLIA of 1967, balked at assignment of its licensure power to any other HEW agency. In my view subsequent attempts of interagency cooperation by HEW have been no more promising—clearly implying the need for the establishment of the Office of Clinical Laboratories.

Needless to say, in the traditional way of the Congress there are some differences between the Senate and House viewpoints on clinical laboratory improvement legislation. There is some disagreement as to whether or not there needs to be a separate Office of Clinical Laboratories, whether or not there should be an advisory council, whether or not citizens' suits should be permitted, whether or not insurance companies or blood banks should be included and whether or not physicians' offices should be affected.

However, there is no disagreement on the need for this legislation.

Medical laboratory testing occupies an increasingly vital place in both diagnostic and preventive medicine. Nearly five billion tests are done annually, costing the American people over $12 billion plus—eight to ten percent of the annual expenditure for medical care.

It is also in this area that the individual is most vulnerable In our system of medical care, which has become increasingly complex and technologically oriented, we must place our trust in an individual practitioner in order to be guided through the maze of diagnostic tools and therapies. But even this professional in whom we place so much trust cannot use these tools effectively without a reliable series of laboratory tests. In the key area of determining a diagnosis upon which an entire course of treatment and even a human life will rest, the laboratory is where the rubber meets the road.

Every day millions of laboratory tests are conducted, and every American is entitled to protection from inaccurate and unreliable results because of a failure of laboratories to observe basic quality standards and procedures. The consequence of laboratory deficiencies in terms of human suffering are severe and tragic. At the same time the consequences of fraud and abuse can be just as devastating to the economic well being of the individual and the medical care delivery system.

The need for reform is obvious, and I believe that the Clinical Laboratory Improvement Act will make a new day in the quality of medical care for all of us.

I have attached to my testimony a brief summary of the major provisions of S. 705, the Clinical Laboratory Improvement Act of 1978, as it passed the Senate on July 28.

Again, my thanks and my appreciation to your Chairman, Mr. Rostenkowski and Ranking Minority member, Mr. Duncan, and to Chairman of the full Ways and Means Committee, Mr. Ullman, the Ranking Minority Member, Mr. Barber Conable of New York.

SUMMARY—S. 705, THE CLINICAL LABORATORY IMPROVEMENT ACT OF 1978

As passed by the Senate, S.705 would—

(1) extend and expand the existing program of mandatory licensure to all laboratories (except those under the jurisdiction of the Department of Defense or the Veterans' Administration) soliciting and accepting specimens for laboratory analysis;

(2) authorize the Secretary of Health, Education, and Welfare (hereinafter referred to as Secretary) to license those laboratories meeting quality assurance standards;

(3) authorize the Secretary to promulgate standards and regulations to assure the quality, accuracy, and reliability of laboratory testing;

(4) authorize the Secretary to delegate his licensure authority to states with primary enforcement responsibility to implement laboratory quality assurance programs at least equal to the federal program;

(5) authorize the Secretary and any state with primary enforcement responsibility to take necessary actions against laboratories not meeting the quality assurance standards;

(6) authorize the Secretary to establish an Office of Clinical Laboratories, the purpose of which would be to establish a uniform regulatory program for all laboratories subject to federal jurisdiction;

(7) authorize the Secretary to establish an advisory council to advise, consult with, and make recommendations to the Office of Clinical Laboratories concerning the development of quality assurance standards and the implementation of such standards;

(8) authorize the Secretary to exempt physicians' office laboratories under certain conditions where physicians file an attested application with the Secretary, including but not limited to a description of the qualifications of non-physician laboratory personnel, the quality and type of tests conducted, and the score of proficiency examinations taken by such personnel; or where such laboratory participates in an approved proficiency testing program;

(9) authorize the Secretary to waive from the personnel standards laboratories located in and serving rural areas;

(10) authorize the Secretary and any state with primary enforcement responsibility to utilize the services of private, nonprofit entities for the provision of inspection and proficiency testing services;

(11) authorize $15,000,000 annually to permit the Secretary to provide technical and financial assistance to states to become states with primary enforcement responsibility;

(12) authorize the Secretary to inspect laboratories without a warrant solely for the purpose of determining compliance with the promulgated national standards;

(13) authorize the Secretary to seek revocation of a laboratory's license where it is found that the laboratory has engaged in kickbacks, bribes, or false, fictitious, or fraudulent billing practices;

(14) prohibit discrimination by any licensed laboratory against any employee who has become involved in any activity concerning allegations that the laboratory is in violation of this section;

(15) authorize the Secretary to exempt laboratories which are primarily engaged in biomedical or behavioral research;

(16) authorize the Secretary to exempt laboratories where the sole purpose of the tests or procedures performed is to determine insurability for the business of insurance;

(17) authorize $1,000,000 annually to permit the Secretary to make grants and contracts for projects and studies respecting clinical laboratory methodology and utilization;

(18) authorize increased penalties for failure to comply with the national standards and for any fraudulent activities undertaken in connection with obtaining reimbursement under titles XVIII and XIX of the Social Security Act;

(19) authorize one-year experimental demonstration competitive bidding in state medicaid programs under title XIX of the Social Security Act; and

(20) authorize citizen suits for alleged violation of compliance with the law.

Mr. ROSTENKOWSKI. Thank you, Senator.

We certainly welcome the air of cooperation that you bring to this subcommittee. It is certainly our intention to improve the bill, and to

toughen it where we feel it is necessary. I think we all agree that the inside deal is something we want to eliminate, and I am sure this committee will work toward that goal.

Mr. Corman?

Mr. CORMAN. Thank you, Mr. Chairman.

Senator, I do not know if this is the appropriate piece of legislation, but I wanted to call to your attention a concern of mine, which we must address sooner or later. Every time we save money for medicare, we save it just for the Government. We do not save it for the beneficiary. And this morning, first of all, the Government proposes to look and see if the charge was the lowest reasonable charge, and whether or not the procedure was called for. But that does not determine what the patient has to pay. The patient has to pay whatever the doctor decides to charge.

There is a rapid decrease of benefit to medicare recipients because of this. We can no longer satisfy ourselves with saving money for the trust fund, at the expense of the patient.

The patient has absolutely no control over what kind of tests are given or what they cost, and whatever is left over after the Government decides that they have paid all they are going to, comes out of the beneficiary's pocket.

I call that to your attention and welcome any suggestion you have.

Senator JAVITS. We have tried to do something about that by requiring in the billing practice an accounting of who gets the money and, for example, what has been billed the doctor, if he doesn't do his own testing. That is some measure of an effort to get abreast of that situation.

In addition, the mere fact that we are reaching out to all the testing agencies, even doctors, whether he can accept some number of patients in order to cut down the aggregate number or not, I think will bring a better sense of discipline into the field.

In addition, I think we all know, 10 percent of people are chiselers; 90 percent are decent people.

Really one of the big things I tried in fashioning this bill was to require people who render the service to face themselves. If a doctor, or the director of a laboratory, has to certify as to the individual personnel and the individual charges, he is going to think twice before he signs his name to that paper about what he is charging and what the deal is and what the personnel is and how well trained they are.

It is different than today when nobody is asking any questions.

I think we will do something to try to get abreast of that, Jim, but I don't want to give you any idea that we intend one of these iron, riveted regulations. It just costs too much and would be too tough. We are going to start softer and see how it works.

Mr. ROSTENKOWSKI. Mr. Duncan?

Mr. DUNCAN. I have no questions, Mr. Chairman.

I want to thank the Senator for being here. You certainly have been most helpful.

Mr. ROSTENKOWSKI. Mr. Burleson.

Mr. BURLESON. I am glad to see you Senator. We have a long friendship and association, and I appreciate your being here.

Senator JAVITS. Thank you.

Mr. ROSTENKOWSKI. Mr. Cotter?

Mr. COTTER. We are glad to have the Senator here.

Mr. ROSTENKOWSKI. Mr. Gradison?

Mr. GRADISON. I hope we can move quickly with our part of the markup so that it may come to the floor before long.

Thank you, Mr. Chairman.

Senator JAVITS. Mr. Chairman, may I say that this failed in the last Congress only because of time, and I can't tell the chairman and the ranking member how deeply I appreciate their willingness to put this on. I know you are loaded, and he did it because he agrees with you, Mr. Gradison.

Mr. GRADISON. He likes 8 o'clock in the morning.

Mr. ROSTENKOWSKI. Dr. Shapiro.

Welcome to the committee, Doctor. If you will, identify yourself and your association, and then proceed with your testimony.

STATEMENT OF DR. BARRY SHAPIRO, CHAIRMAN-ELECT, BOARD OF MEDICAL ADVISERS, AMERICAN ASSOCIATION FOR RESPIRATORY THERAPY, ACCOMPANIED BY SANDRA PARKISON, EXECUTIVE DIRECTOR

Dr. SHAPIRO. Thank you, Mr. Chairman. My name is Barry Shapiro. I am an anesthesiologist. I am chairman-elect of the board of medical advisers of the American Association for Respiratory Therapy, and I am accompanied by Mrs. Sandra Parkison, executive director of AART. The American Association for Respiratory Therapy represents approximately 20,000 certified respiratory therapy technicians and registered respiratory therapists and is jointly sponsored by the American College of Chest Physicians, the American Society of Anesthesiologists, and the American Thoracic Society.

Mr. Chairman, I fully understand that your subcommittee is primarily interested in those provisions of H.R. 10909 which directly affect the medicare program. I think it is vital, though, for the subcommittee to fully appreciate the impact of certain sections of H.R. 10909.

AART fully supports the legislative intent of the Clinical Laboratory Improvement Act which, as we interpret it, is designed through licensure and standards, to be a positive step toward assurance of accurate laboratory testing throughout this country's 7,000 hospitals. As a physician I must readily admit my hesitancy to support Federal regulations in the delivery of health care, but I think the data strongly indicate the need to establish guidelines by which laboratory testing will be performed.

The specialty of cardiopulmonary function testing, however, complicates the matter. Testing procedures which involve such technical matters as pulmonary function testing, blood gas measurements, and cardiac catheterization measurements demand highly specialized physicians supported by additional highly specialized technicians.

I would like to emphasize that we do not seek exemption from these regulations, but rather special guidelines and separate regulations for these special laboratories.

When we look specifically at the specialty of pulmonary function testing, the present analysis of the health delivery system indicates that 92 percent of all hospitals which perform pulmonary function testing on the premises do so not as an integral part of the clinical

laboratory per se but rather as a separate and clearly distinct function of the respiratory therapy department. It is clear that the specialized training of respiratory therapists to perform their highly technical work differs from the professional training of laboratory technicians.

In a day when we are all very concerned about the costs of health care, the AART cannot even anticipate the costs in dollars, as well as quality, which could be incurred if laboratory technicians were required to perform such cardiopulmonary function testing. I sincerely believe that patient care would be adversely affected by such a move and feel that no Member of Congress would legislate such regulations which would so affect the health of the people of this country.

The uniqueness of cardiopulmonary function testing was noted by Chairman Rogers and other cosponsors of H.R. 10909 when they clearly noted the highly specialized nature of this facet of laboratory testing. In fact, we are encouraged by the Commerce Committee efforts to mandate an HEW study, section 104 of H.R. 10909, which will assist the AART and other professional groups to assess the quality of testing in specialized laboratories. The AART and its medical sponsors are fully aware of the benefits which could be served by development of guidelines and standards which would apply to cardiopulmonary function laboratories as well as the proposed standards for the more general scope of clinical laboratories.

As a matter of fact, the AART is just about to complete a Federal grant through the Bureau of Health Manpower which examines the whole issue of credentialing respiratory therapists and respiratory therapy technicians. Although the final report is not due until next month, my understanding is that the report strongly recommends a specific role delineation, or perhaps we could better call it a job description with specific levels of competence that respiratory therapy professionals should, and must, meet.

AART is willing to take the initiative to develop with the appropriate HEW representatives necessary standards for cardiopulmonary function laboratories. But, I emphasize again, it is my opinion that we cannot run the risk of integrating two specialties in critical areas of the health delivery system without running into significant cost and more importantly an open risk to the quality of health care in our Nation's hospitals.

Mr. Chairman, for these reasons AART fully supports H.R. 10909 as written and urges the Health Subcommittee to support the Commerce Committee version of H.R. 10909 which recognizes cardiopulmonary function laboratories as distinct and separate units because of the highly technical nature of the work performed.

Thank you for the opportunity of speaking. We will be glad to answer questions.

Mr. ROSTENKOWSKI. Thank you, Doctor.

Mr. Corman?

Mr. Duncan, do you care to ask questions?

Mr. DUNCAN. Thank you, Mr. Chairman.

Doctor, do you believe the exemption in H.R. 10909 for highly specialized laboratories could be achieved by regulation?

Dr. SHAPIRO. I don't interpret that the bill asks for an exemption, but rather the consideration for separate and specific guidelines for regulating the cardiopulmonary function laboratories.

Mr. DUNCAN. It exempts the pulmonary and cardiac laboratories for 2 years.

Dr. SHAPIRO. It would give time to look at the regulations that should be set for these laboratories. The nature of them, the physicians involved, the technicians, and the technologists involved, and the special problems of laboratory testing with patients in the laboratory are those which I believe, strongly, have to come under separate regulations and guidelines from those of the general clinical laboratory.

Mr. DUNCAN. Do you find personnel working in laboratories well qualified and well trained?

Dr. SHAPIRO. My experience is in cardiac laboratories, and in my experience they are well qualified.

Mr. DUNCAN. Have you heard otherwise?

Dr. SHAPIRO. Yes.

Mr. DUNCAN. Would you care to expand on that?

Dr. SHAPIRO. I am sure the "otherwise" exists, and I am sure regulations are appropriate.

I am in agreement with the intent of the bill.

I think, however, it would be a very grave mistake to include in general regulations and guidelines set for clinical laboratories, for the specialized cardiopulmonary function laboratories to fall under those regulations.

Mr. DUNCAN. What State do you practice in?

Dr. SHAPIRO. Illinois; Chicago.

I know there is strong county, city, and State regulation. I am not aware of the laws themselves.

Mr. DUNCAN. Do you think they do a reasonably good job?

Dr. SHAPIRO. I think the quality of the laboratories I have been in contact with in Chicago are quite good.

Mr. DUNCAN. Thank you, Mr. Chairman.

Mr. ROSTENKOWSKI. Mr. Burleson?

Mr. Cotter?

Thank you, Doctor.

Dr. Harris?

Welcome, Doctor. If you will, identify yourself and your association and proceed with your testimony.

STATEMENT OF DR. T. REGINALD HARRIS, MEMBER, BOARD OF TRUSTEES, AMERICAN SOCIETY OF INTERNAL MEDICINE, ACCOMPANIED BY MARK LEASURE, DIRECTOR OF LIAISON

Dr. HARRIS. I am Reggie Harris, a member of the Board of Trustees of the American Society of Internal Medicine. I practice internal medicine, providing mostly primary care, in Shelby, N.C. With me today is Mark Leasure, ASIM director of liaison.

The American Society of Internal Medicine is a federation of 51 State component societies representing more than 15,000 internists who, by training and practice standards, are recognized as specialists in internal medicine.

Our purpose in coming is to testify on section 202(a)(1) of H.R. 10909, which sets forth billing and reimbursement requirements for laboratory services under medicare.

I would like to summarize my written statement, which has been submitted for the record.

Originally we thought these provisions were reasonably sound. However, on further analysis, we believe passage of section 202(a)(1) as presently constituted will disrupt the provision of laboratory services to our medicare patients and increase costs to both the program and patients.

Our opposition was prompted largely by "Medicare Transmittal No. 628," dated March 1978, a copy of which we recently supplied to your committee staff. Based on conversations with your staff and with DHEW officials, we believe this transmittal reflects the way DHEW will implement the provisions in section 202(a)(1).

As stated above, this section calls for a "nominal fee" for collecting and handling a lab specimen. The transmittal, however, prohibits payment of such a fee unless the physician has customarily listed collecting and handling charges separately and this is the standard practice locally. My patients would, therefore, receive no reimbursement for my collecting and handling charges, nor, according to an informal survey we conducted, would the patients of more than half of the internists in the Nation.

In addition, the transmittal established a $3 nationwide limit on medicare reimbursement for collecting and handling in cases where any reimbursement is allowed. We have informed HCFA officials that we believe these provisions will have many adverse consequences, but have received no indication of plans to change them.

Just yesterday, we were informed that they intend to modify the transmittal to permit payment for collecting and handling charges in those cases in which the physician previously included the cost for this service in a single lab charge. This change corrects only part of the problem.

The $3 maximum will create problems which I will explain later.

The stated reasons behind the changes proposed in this section are to reduce program costs by eliminating unreasonable markups on lab charges. We concur wholeheartedly with this objective.

Full understanding of the realities of charging for lab tests makes it clear that the legislative remedy prescribed is unwarranted and not in the public interest. There are three components involved when a physician bills for a test performed by an outside lab:

No. 1. The cost of the test; that is, what the lab charges the physician.

No. 2. The cost of collecting, processing, and handling the specimen and related overhead.

No. 3. The physician's professional interpretation of the test results.

How physicians bill for these components varies. In most areas, professional interpretation is included in the charge for the office visit, but the cost of collecting and handling is added to the cost of the lab test. This explains many so-called markups.

In some areas, the professional interpretation component is also added to the charge for the lab test (and fees for office visits are correspondingly lower). Both practices are accepted by third-party carriers. In North Carolina where I practice, and in most parts of the country, we combine the cost of a test performed outside our office and of collecting, handling, and related overhead into one charge. To put

section 202(a) (1) in the perspective of actual patient care, I would like to explain the effects it will have on my medicare patients and on medicare program costs.

I have prepared a chart to indicate the costs of one of the most common lab tests, the SMA–12, as provided through my office now and as it would be under the provisions outlined in the bill.

I frequently have these tests done at Biomedical Laboratories, 150 miles away, in Burlington, N.C. I am charged $5 for the SMA–12—other tests cost $10, $15, or more. I add $5 to cover my cost and bill the patient $10. My $5 charge covers the costs of the following: a technician's time spent in collecting and handling the specimen; any special preparation of the specimen; costs of labeling including providing information about the patient, physician, diagnosis, and the medicare number; the space required for all of this; billing costs; bad debt expense; and, for many medicare patients, extra attention and assistance from the receptionist and/or the nurse.

The first horizontal line in the chart depicts my current practice. The outside laboratory charge of $5 is added to my physician's charge of $5 for my total laboratory charge of $10. Medicare reimburses the patient $8 (80 percent of the actual charge), and the patient pays $2.

Under the provisions of the bill and medicare transmittal No. 628, I have several options for providing this laboratory service. Under option No. 1, if I bill the patient for the laboratory service, a $5 laboratory fee would be allowed, but my $5 collecting and handling charge would be totally disallowed because I have not customarily identified this as a separate charge. In this instance, medicare would pay $4 (again, 80 percent of the actual charge) and the patient would be asked to pay $6. This would shift $4 in cost from the medicare program to my patient, which is clearly contrary to the purpose of the medicare program.

Should the $3 collecting and handling charge allowed by the transmittal under certain circumstances be made applicable to me, and if I continued to bill for both components of the laboratory charge, option No. 2 on the chart would apply. Medicare would pay 80 percent of the lab's $5 charge and 80 percent of the $3 allowance for collecting and handling for a total of $6.40. The patient would be required to pay $3.60. This would shift $1.60 from the medicare program to the patient.

However, this is an option that physicians who understand the billing and reimbursement process would not select. By selecting this option, physicians would be forcing their patients to pay more out of pocket. In addition, it simply makes no economic sense for physicians to do the billing for the laboratory (and assume the risks of bad debts connected with it) when the reimbursement for collecting and handling is inadequate. Instead, I would let the laboratory bill the patient itself. This is option No. 3.

In this case, when the laboratory I use bills the patient directly, it charges $10 for the SMA–12. I would bill the patient only for my collecting and handling charges, $5, making a total charge of $15. Medicare would pay $8 of the lab's $10 charge, and $2.40 of my $5 charge, for a total of $10.40. The patient would pay $4.60.

This option increases the medicare payment by $2.40 and the patient's cost by $2.60, for a total increased cost of $5. And these figures

do not take into account increased administrative costs for carriers of processing two claims instead of one.

Another option in some areas would be to send the patient to the independent lab to have the specimen taken. However, this causes added inconvenience and cost to the medicare patients. In many cases, independent labs charge more for collecting and billing than do physicians. I haven't listed this option on the chart because in my area the lab is 150 miles away.

My fourth option is to send the patient to the hospital laboratory for the entire procedure, including collecting and handling, performing the test, and billing. The total charge for an SMA–12 in my hospital is now $15.45, of which $12.36, would be paid by the medicare program and $3.09 by the patient. This is an increase of $4.36 for medicare and $1.09 for my patient over current costs. This results in a total increased cost of $5.45 and also requires a possibly difficult trip to the hospital by my patient.

I would choose the last option in most cases because it requires the least out-of-pocket expense to my patient and, frankly, because I could avoid the administrative hassles present in other options. If it is difficult for the patient to make the trip to the hospital, I would probably choose option No. 3. Either option increases costs and adds to the inconvenience and confusion of the patient.

Nor is this an isolated example. My situation is typical. ASIM members from around the Nation have responded to information we have provided them on proposed changes in lab reimbursement with similar examples of how the changes would significantly increase costs to both medicare patients and carriers as well as make it more difficult for physicians to provide and patients to obtain quality care. Such will be the result if section 202(a)(1) is adopted and implemented as suggested in the medicare transmittal.

We believe these problems can be avoided by deleting the alternative of reimbursement based on the amount billed by the outside laboratory plus a nominal fee. We have shown that this provision would force physicians to change their practice in a way that would result in increased costs, et cetera. We would suggest amending parts (2) and (3) of proposed section 1842(h) to read as presented in our written statement.

The requirements that physicians report the lab's charge also have been deleted in this amended version. We believe these are unnecessary if the lab itself is identified, because the carriers can identify charges for tests billed by physicians. This gives them the capability of determining if the total amount billed is reasonable.

We are also concerned that the viability of physicians' office labs could be jeopardized if DHEW implements section 202(a)(1) as we expect it to. It is extremely important to recognize that some tests needed quickly for day-to-day management of patients must be performed in physicians' offices.

There is the example of the diabetic patient whose hospitalization is avoided because of the readily available blood sugar tests, and the patient with fever, and the lab tests indicate infectious mono rather than leukemia.

These may be more expensive than other similar tests that can be done sometime later in an outside lab. "Reasonable charge" determina-

tions that ignore the distinctions between these two kinds of tests may make reimbursement for tests performed in physicians' offices inadequate. This would undermine the economic viability of maintaining such labs and thereby limit access of medicare patients to essential laboratory services. The net result would be lower quality care at increased cost to both the patient and the medicare program.

We are fearful that this may occur as a result of the provision in the bill that provides for reimbursement for office lab tests according to "reasonable charge" determinations. The provision fails to direct that reasonable charges for the different kind of lab test be determined separately, and the above-mentioned medicare transmittal has specifically prohibited this. We believe the subcommittee would be remiss in not stating clearly its intention to preserve the viability of physicans' office labs.

In summary, we believe DHEW's implementation of section 202 (a) (1) in its present form would disrupt the provision of laboratory services to medicare patients and lead to increased costs to both the patient and the medicare program. We believe this can be avoided, and the medicare program can still limit payment for unreasonable lab fees if the recommendations outlined above are adopted. We stand ready to assist in any way we can.

Thank you for the opportunity to present our views. I would be happy to answer any questions you have.

[The prepared statement follows:]

STATEMENT OF THE AMERICAN SOCIETY OF INTERNAL MEDICINE

I am Reggie Harris, a member of the Board of Trustees of the American Society of Internal Medicine (ASIM). I practice internal medicine, providing mostly primary care, in Shelby, North Carolina. With me today is Mark Leasure, ASIM Director of Liaison.

The American Society of Internal Medicine (ASIM) is a federation of 51 state component societies representing more than 15,000 internists who, by training and practice standards, are recognized as specialists in internal medicine.

Our purpose in coming is to testify on Section 202(a) (1) of HR 10909, which sets forth billing and reimbursement requirements for laboratory services under Medicare. This Section establishes the following requirements:

If the physician's bill identifies the outside lab and its charge to the physician, Medicare will pay either the lab's charge plus a "nominal fee" to cover collecting and handling costs, or the "reasonable" charge, whichever is lower.

If a physician's bill does not identify the lab and its charge to the physician, Medicare will pay the lowest amount for which the carrier estimates the physician could have obtained the test "in the applicable locality."

If the bill indicates that the test was performed by or under the supervision of the physician, reimbursement will be according to "reasonable" charge determinations.

Originally we thought these provisions were reasonably sound. However, on further analysis, we believe passage of Section 202(a) (1) as presently constituted will disrupt the provision of laboratory services to our Medicare patients and increase costs to both the program and patients. Our opposition was prompted largely by Medicare Transmittal #628 (dated March 1978), a copy of which we recently supplied to your Committee staff. Based on conversations with your staff and with DHEW officials, we believe this Transmittal reflects the way DHEW will implement the provisions in Section 202(a) (1). As stated above, this Section calls for a "nominal fee" for collecting and handling a lab specimen. The Transmittal, however, prohibits payment of such a fee unless the physician has customarily listed collecting and handling charges separately and this is the standard practice locally. My patients would therefore receive no reimbursement for my collecting and handling charges, nor, according to an informal survey we conducted, would the patients of more than half of the internists in the nation.

In addition, the Transmittal established a $3 nationwide limit on Medicare reimbursement for collecting and handling in cases where any reimbursement is allowed. We have informed HCFA officials that we believe these provisions will have many adverse consequences but have received no indication of plans to change them. HCFA officials apparently either consider these provisions to be consistent with those in Section 202(a)(1) or they are implementing a complex administrative system that will need to be changed when CLIA is enacted.

The stated reasons behind the changes proposed in this Section are to reduce program costs by eliminating unreasonable "mark-ups" on lab charges. We concur wholeheartedly with this objective. However, the approach taken by Section 202(a)(1) is based largely on a report released by the Comptroller General in August 1976 titled "Tighter Controls Needed Over Payment for Laboratory Services under Medicare and Medicaid." The report claims to have found a pattern of "exorbitant mark-ups" by physicians on lab charges. This conclusion was based on a comparison between what labs charge physicians for performing tests and what physicians charge patients for the same tests. It assumes incorrectly that all of the differences are the result of unreasonable mark-ups. The report fails to take into consideration why physicians charge patients more than they are billed by the labs and what labs would charge patients if they had to collect and handle specimens and bill patients directly. The report's failure to take such important factors into account makes it a poor basis for development of an approach for ending unreasonable mark-ups.

Full understanding of the realities of charging for lab tests makes it clear that the legislative remedy prescribed is unwarranted and not in the public interest. There are three components involved when a physician bills for a test performed by an outside lab:

1. The cost of the test (i.e. what the lab charges the physician).
2. The cost of collecting, processing and handling the specimen and related overhead.
3. The physician's professional interpretation of the test results.

How physicians bill for these components varies. In most areas, professional interpretation is included in the charge for the office visit, but the cost of collecting and handling is added to the cost of the lab test. This explains many so-called "mark-ups." In some areas, the professional interpretation component is also added to the charge for the lab test (and fees for office visits are correspondingly lower). Both practices are accepted by third-party carriers. In North Carolina, where I practice, and in most parts of the country, we combine the cost of a test performed outside our office and of collecting, handling and related overhead into one charge. To put Section 202(a)(1) in the perspective of actual patient care, I would like to explain the effects it will have on my Medicare patients and on Medicare program costs.

I have prepared a chart (a copy is attached) to indicate the costs of one of the most common lab tests, the SMA–12, as provided through my office now and as it would be under the provisions outlined in the bill.

I frequently have these tests done at Biomedical Laboratories, 150 miles away, in Burlington, North Carolina. I am charged $5 for the SMA–12 (other tests cost $10, $15, or more). I add $5 to cover my costs and bill the patient $10. My $5 charge covers the costs of the following: a technician's time spent in collecting and handling the specimen; any special preparation of the specimen; costs of labeling including providing information about the patient, physician, diagnosis, and the Medicare number; the space required for all of this; billing costs; bad debt expense; and, for many Medicare patients, extra attention and assistance from the receptionist and/or the nurse.

The first horizontal line in the chart depicts my current practice. The outside laboratory charge of $5 is added to my physician's charge of $5 for my total laboratory charge of $10. Medicare reimburses the patient $8 (80 percent of the actual charge), and the patient pays $2.

Under the provisions of the bill and Medicare Transmittal #628, I have several options for providing this laboratory service. Under Option #1, if I bill the patient for the laboratory service, a $5 laboratory fee would be allowed but my $5 collecting and handling charge would be totally disallowed because I have not customarily identified this as a separate charge. In this instance, Medicare would pay $4 (again, 80 percent of the actual charge) and the patient would be asked to pay $6. This would shift $4 in cost from the Medicare program to my patient, which is clearly contrary to the purpose of the Medicare program.

Should the $3 collecting and handling charge allowed by the Transmittal under certain circumstances be made applicable to me, and if I continued to bill for both components of the laboratory charge, Option #2 on the chart would apply. Medicare would pay 80 percent of the lab's $5 charge and 80 percent of the $3 allowance for collecting and handling for a total of $6.40. The patient would be required to pay $3.60. This would shift $1.60 from the Medicare program to the patient.

However, this is an option that physicians who understand the billing and reimbursement process would not select. By selecting this option, physicians would be forcing their patients to pay more out-of-pocket. In addition, it simply makes no economic sense for physicians to do the billing for the laboratory (and assume the risks of bad debts connected with it) when the reimbursement for collecting and handling is inadequate. Instead, I would let the laboratory bill the patient itself. This is Option #3. In this case, when the laboratory I use bills the patient directly, it charges $10 for the SMA–12. I would bill the patient only for my collecting and handling charges, $5, making a total charge of $15. Medicare would pay $8 of the lab's $10 charge, and $2.40 of my $5 charge, for a total of $10.40. The patient would pay $4.60. This option increases the Medicare payment by $2.40 and the patient's cost by $2.60, for a total increased cost of $5. And these figures do not take into account increased administrative costs for carriers of processing two claims instead of one.

Another option in some areas would be to send the patient to the independent lab to have the specimen taken. However, this causes added inconvenience and cost to the Medicare patients. In many cases independent labs charge more for collecting and billing than do physicians. I haven't listed this option on the chart because in my area, the lab is 150 miles away.

My fourth option is to send the patient to the hospital laboratory for the entire procedure, including collecting and handling, performing the test, and billing. The total charge for an SMA–12 in my hospital is now $15.45, of which $12.36 would be paid by the Medicare program and $3.09 by the patient. This is an increase of $4.36 for Medicare and $1.09 for my patient over current costs. This results in a total increased cost of $5.45 and also requires a possibly difficult trip to the hospital by my patient.

I would choose the last option in most cases because it requires the least out-of-pocket expense to my patient and, frankly, because I could avoid the administrative hassles present in the other options. If it is difficult for the patient to make the trip to the hospital, I would probably choose Option #3. Either option increases costs and adds to the inconvenience and confusion of the patient.

Nor is this an isolated example. My situation is typical; ASIM members from around the nation have responded to information we've provided them on proposed changes in lab reimbursement with similar examples of how the changes would significantly increase costs to both Medicare patients and carriers as well as make it more difficult for physicians to provide and patients to obtain quality care. Such will be the result if Section 202(a)(1) is adopted and implemented as suggested in the Medicare Transmittal.

We believe these problems can be avoided by deleting the alternative of reimbursement based on the amount billed by the outside laboratory plus a nominal fee. (We have shown that this provision would force physicians to change their practice in a way that would result in increased costs, etc.) We would suggest amending parts (2) and (3) of proposed Section 1842(h) read as follows:

"(2) If the bill or request for payment indicates that such services were performed by a laboratory, and identifies such laboratory, payment for such services shall be the reasonable charge for such services."

"(3) If the bill or request for payment (A) does not indicate who performed such services, or (B) indicates that such services were performed by a laboratory but does not identify the laboratory, payment shall be the lowest charge at which the carrier estimates such services could have been secured by a physician from a laboratory in the applicable locality."

The requirements that physicians report the lab's charge also have been deleted in this amended version. We believe these are unnecessary if the lab itself is identified, because the carriers can identify charges for tests billed by physicians. This gives them the capability of determining if the total amount billed is reasonable.

We are also concerned that the viability of physicians' office labs could be jeopardized if DHEW implements Section 202(a)(1) as we expect it to. It is extremely important to recognize that some tests needed quickly for day-to-day

management of patients must be performed in physicians' offices. These may be more expensive than other similar tests that can be done some time later in an outside lab. "Reasonable charge" determinations that ignore the distinctions between these two kinds of tests may make reimbursement for tests performed in physicians' offices inadequate. This would undermine the economic viability of maintaining such labs and thereby limit access of Medicare patients to essential laboratory services. The net result would be lower quality care at increased cost to both the patient and the Medicare program.

We are fearful that this may occur as a result of the provision in the bill that provides for reimbursement for office lab tests according to "reasonable charge" determinations. The provision fails to direct that reasonable charges for the different kind of lab test be determined separately, and the above-mentioned Medicare Transmittal has specifically prohibited this. We believe the Subcommittee would be remiss in not stating clearly its intention to preserve the viability of physicians' office labs.

In summary, we believe DHEW's implementation of Section 202(a)(1) in its present form would disrupt the provision of laboratory services to Medicare patients and lead to increased costs to both the patient and the Medicare program. We believe this can be avoided, and the Medicare program can still limit payment for reasonable lab fees if the recommendations outlined above are adopted. We stand ready to assist in any way we can.

Thank you for the opportunity to present our views. I would be happy to answer any questions you have.

COSTS OF HAVING AN SMA-12 PERFORMED UNDER VARIOUS REIMBURSEMENT ALTERNATIVES SUGGESTED BY SEC. 202(a)(1) AND MEDICARE TRANSMITTAL 628

How the service is provided and billed	Lab's charge (to physician or to program)	Physician's charge for collecting and handling	Total charge	What medicare pays	What the patient pays	Change in cost to medicare	Increased cost to patient	Total cost increase
Current practice: I collect a specimen, send it to an outside lab for analysis, and bill for both	$5.00	$5	$10.00	[1] $8.00	$2.00			
Option No. 1: Same as above with reimbursement for collection denied	5.00	5	10.00	[2] 4.00	6.00	—$4.00	$4.00	
Option No. 2: Same as above with a maximum of $3 allowed for collection	5.00	5	10.00	[3] 6.40	3.60	—1.60	1.60	
Option No. 3: Same as above, except lab bills patient for the test and I bill for collection. Maximum of $3 for collection allowed	[4] 10.00	5	15.00	[5] 10.40	4.60	2.40	2.60	$5.00
Option No. 4: Patient sent to hospital for collection and hospital bills patient	15.45		15.45	[6] 12.36	3.09	4.36	1.09	5.45

[1] 80 percent times $10.
[2] 80 percent times $5.
[3] 80 percent of $5 plus 80 percent of $3.
[4] What lab will bill program.
[5] 80 percent of $10 plus 80 percent of $3.
[6] 80 percent of $15.45.

Mr. ROSTENKOWSKI. Thank you, Dr. Harris. You refer to the GAO report about payment for lab services under the medicare program.

Comparisons of 1978 lab services for seven physicians in Florida showed that medicare allowed from 117- to 291-percent markup. The amount the lab billed the physician was $350, and the physician billed medicare $965.

Do you still consider this a reasonable amount to recognize for handling?

Dr. HARRIS. The report found this pattern of markups that they referred to. The markups were based on what the lab charged the physi-

cian and what the physician billed the program. It did not take into consideration the cost in the physician's office of handling the patient, collecting the specimen, and the overhead cost of billing and collecting. They were comparing two different groups of procedures.

Mr. ROSTENKOWSKI. Do you still think that increase is ordinary and should be tolerated?

Dr. HARRIS. I couldn't direct myself to the specifics of the amount you referred to. There should be an allowance of the cost in handling the specimen, collecting the specimen, handling the patient, and billing and overhead.

When the outside laboratory does a test, there is a difference when they start with a tube of blood and when you start with the patient with the expenses involved before the blood goes to the laboratory.

This includes the cost of the test itself and ignored those costs related to collecting and handling the specimen and the billing costs.

Mr. ROSTENKOWSKI. Mr. Corman?

Mr. CORMAN. Doctor, I take it you are in private practice?

Dr. HARRIS. Yes.

Mr. CORMAN. Doctor, when you do not take assignments for medicare patients, are you aware of how much of your bill medicare reimburses your patients?

Dr. HARRIS. If I do not take assignments, am I aware of the difference?

Mr. CORMAN. Yes.

Dr. HARRIS. In many cases I am aware of that. I do take assignments, but not in every case. I do in many cases.

Mr. CORMAN. I assume that whether you take an assignment or not is, at least in part, determined by the financial ability of the patient.

Dr. HARRIS. If there seems to be hardship on the patient, or there is a request to take an assignment, we do take an assignment. The truth is that we don't know which patients are medicare patients always. We bill and treat our patients as patients, and we do not necessarily alter our billing practices in accordance with their insurance coverage.

Mr. CORMAN. Do you find that medicare pays the full charge, the portion of it they are supposed to pay?

Dr. HARRIS. That varies depending on what we are talking about. Sometimes the full fee is allowed. In laboratory services my full fee is allowed.

We have found that our method of billing is satisfactory, and they do monitor our performance and they monitor our charges. The chart I presented indicates that our price for the laboratoy test is indeed the same price as the laboratory itself charges, and we also handle and bill and collect the specimen.

Mr. CORMAN. I am worried and I blame both the provider and the trust fund when we see such a large portion of the cost beyond the 20 percent for which they are normally liable. The present system lends itself to medicare insurance becoming less and less valuable for the beneficiaries.

Dr. HARRIS. The present suggestion to us is that if this bill is implemented as HCFA has indicated it will be, what it will do is limit reimbursement, and the cost would be passed on to the patient provided there was no assignment taken.

The problem will be alleviated in many instances by referring the patient to a place where reimbursement is adequate. In this instance, in many of our cases, that would be the hospital laboratory where you ask the patient to get his laboratory procedure there, if there is difficulty providing it in the office.

It has been our experience that charges for laboratory tests in hospital outpatient departments are more than they are in physicians' offices or in outside laboratories. In the instance I cited, as the most widely used outside laboratory test, I believe in the country, in both instances the program would pay more and the patient would pay more.

Mr. CORMAN. That is the present situation? They would allow more if I go to the hospital to get the examination than if I go to your office?

Dr. HARRIS. Yes, sir, that is true presently, and in my experience the laboratory tests provided as an outpatient at the hospital are invariably more expensive than those provided generally elsewhere.

Mr. CORMAN. Thank you very much.

Mr. ROSTENKOWSKI. Mr. Duncan will inquire.

Mr. DUNCAN. No questions, Mr. Chairman.

Mr. ROSTENKOWSKI. Mr. Cotter?

Mr. COTTER. No questions, Mr. Chairman.

Mr. ROSTENKOWSKI. Mr. Martin?

Mr. MARTIN. I arrived near the end of your testimony, and I have been looking through it, and I am interested in the point you are making.

Let me ask you: Generally considering the degree of specialization in most fields of medicine, would you be able to draw a conclusion or would I be able to draw a fair conclusion regarding the quality and reliability of laboratory work done in a general clinical laboratory supervised by a pathologist or a team of pathologists versus that done in private offices? Would one be higher or would the other be higher, or would they be equivalent, or what evaluation might we place on that?

Dr. HARRIS. Quality is a very important issue to us, and I think it would depend on which office and which hospital laboratory you had reference to.

In general, our laboratories and our members are encouraged to participate in a proficiency testing program, and the quality under those circumstances is much higher than in a laboratory which did not participate in such a testing program.

So the quality of the office laboratories is improving as proficiency testing is used. We have previously testified and firmly support proficiency testing for all laboratories regardless of size.

Mr. MARTIN. Generally, would you say that that would be true, that the typical, general average of the private office laboratory would exceed that of the general clinical laboratory in a hospital?

Dr. HARRIS. No, sir, I would not say that. I would say it depends on the individual laboratory.

Mr. MARTIN. But in general, could you make an estimate?

Dr. HARRIS. In general, I would think that the quality of the office laboratory is higher than the—the quality of the hospital laboratory would be higher than the quality of the office laboratory, because of

the great differences in size and availability and procedures done in the two. It would depend on the procedure in many cases, as well as the laboratory.

Mr. MARTIN. Of course, it would depend on the people and their attitude and philosophy?

Dr. HARRIS. Yes.

Mr. MARTIN. But if the laboratory is managed by people under the quality control program of the Council of American Pathologists——

Dr. HARRIS. They have a proficiency testing procedure. For office laboratories it is the program sponsored by the American Society of Internal Medicine, which is sponsored by——

Mr. MARTIN. If this bill is passed and imposes a heavier regulatory burden on the larger laboratory and exempts the smaller laboratory, won't that provide irresistible bias for more and more laboratory work being done in the individual office, perhaps not under the auspices of your organization or its proficiency control program; and if that happens, if the bill is passed with that differentiation wouldn't that tend to lower the quality of the overall reliability of laboratory testing?

Dr. HARRIS. If we assumed people would leave properly supervised laboratories for laboratories that are not properly supervised, that would be true, but I don't think that would happen.

Mr. MARTIN. You don't think there would be enough escalation in cost to do that?

Dr. HARRIS. No; I would think the increased cost to the patients would result in office laboratories discontinuing services that they previously provided, and they would move to the hospital outpatient department where costs are generally higher, and where there is an additional incentive for hospitalization rather than to continue to provide the service in an ambulatory setting.

Mr. MARTIN. Of course, I appreciate your views on that. That gets into a philosophical area, too.

Thank you, Mr. Chairman.

Mr. ROSTENKOWSKI. On page 3 of your testimony you describe the expenses the physician has in connection with lab tests. I assume you mean the diagnosis. I thought the physician was charging for things like the diagnosis when he charged for an office visit. If this is the trend, as I see it, there is no end to what physicians could be billing separately for.

What are we paying for really when we pay for an office visit if it isn't the diagnosis?

Dr. HARRIS. On page 4, I add an explanation. In some areas the professional interpretation is included in the lab test. In my area and in most areas of the country a separate charge is not made for the professional interpretation nor is it included in there as an extra charge.

The charges generally included in the laboratory test include handling the patient, drawing and collecting the specimen, running the test, and there is no charge made for professional interpretation in most parts of the country. People do not always come for a test at the time of the office visit. There is not a separate office visit or diagnosis or professional visit charged in many trips to the physician's office for a laboratory test.

There is no additional professional charge, as you suggested, for examination of the patient.

Mr. ROSTENKOWSKI. Thank you, Dr. Harris.

Are there any other questions?

Thank you very much.

This concludes the public testimony on the clinical labs bill. I thank you all for participating.

There will be no need for a meeting of this subcommittee on Thursday next. This subcommittee stands adjourned.

[Whereupon, at 10:25 a.m., the hearing was adjourned.]

[The following was submitted for the record:]

AMERICAN ASSOCIATION OF BLOOD BANKS,
Washington, D.C., May 18, 1978.

Hon. DAN ROSTENKOWSKI,
Chairman, Subcommittee on Health,
House Ways and Means Committee,
Washington, D.C.

DEAR CONGRESSMAN ROSTENKOWSKI: It is my understanding that testimony before your Subcommittee last week on the Clinical Laboratories Improvement Act (H.R. 10909) urged that hospital blood banks be included within the scope of the Act. At the present time, H.R. 10909 exempts all blood banks, whether they be free-standing or hospital based.

The position of the American Association of Blood Banks (AABB) on this issue is that all blood banks should be treated similarly by the Act; that is, all should be regulated by CLIA or none should be.

The AABB, therefore, supports H.R. 10909 as reported from the House Committee on Interstate and Foreign Commerce.

As you may know, the AABB represents over 2,000 nonprofit hospital and community blood banks and over 5,000 individual blood bankers. It actively promotes better patient care through many programs, including Education, Inspection and Accreditation, Publications and Scientific. Its Standards and Technical Manual are accepted by blood bankers around the world and have been officially adopted for use by the Department of Defense.

Sincerely yours,

HOWARD F. TASWELL, M.D.,
President.

AMERICAN COLLEGE OF NUCLEAR PHYSICIANS,
Washington, D.C., May 15, 1978.

Hon. DAN ROSTENKOWSKI,
U.S. House of Representatives,
Rayburn House Office Building,
Washington, D.C.

DEAR CONGRESSMAN ROSTENKOWSKI: The American College of Nuclear Physicians is pleased to submit its statement on H.R. 10909, the Clinical Laboratory Improvement Act of 1978.

As we discussed with you at our annual meeting in San Francisco, nuclear medicine is a highly technical, diagnostic specialty. Since nuclear medicine laboratories would be regulated by the Act, the ACNP would be anxious and willing to assist in giving guidance to the Secretary in establishing the proper standards for these specialized laboratories, as well as serving in an advisory capacity during the required study of highly specialized laboratories.

However, it is our feeling that the need for a study of highly specialized laboratories suggests that the current level of knowledge within the HEW to set proper standards is not sufficient. Therefore, we would urge that all highly specialized laboratories be exempt during the two year study period and until such time as proper standards can be set.

Sincerely.

RICHARD. C. REBA, M.D.
Immediate Past President,
Chairman, Government Affairs Committee.

Enclosure.

STATEMENT OF THE AMERICAN COLLEGE OF NUCLEAR PHYSICIANS

This statement is made on behalf of the American College of Nuclear Physicians (ACNP) which represents approximately 1,000 physicians engaged in the practice of nuclear medicine, primarily a diagnostic medical discipline.

The ACNP feels that the amendments to Title XIX of the Social Security Act, which provide for the establishment of a competitive bidding process for clinical laboratory services, would reduce the quality of medical care currently available. A physician may use more than one clinical laboratory in his practice based on reliable experience on the performance of various procedures. Requiring the physician to use only those laboratories that have been awarded a contract under the competitive bidding system interferes with his judgment and could lead to a reduction of services for medical care paid for under the Social Security Act. It is our feeling that once a laboratory has been certified as meeting National Standards, it should be able to be of service to any physician.

In addition to the amendments affecting title II of the act, ACNP is concerned over another aspect of the bill. Section 372(c)(5) exempts from the national standards any highly specialized clinical laboratories. If it is the feeling of Congress that HEW needs a study to determine proper regulations for all highly specialized clinical laboratories, then perhaps all highly specialized clinical laboratories should be exempt from the standards until the study is completed. The need for the study suggests that perhaps at this point in time HEW is not capable of setting standards for highly specialized laboratories. Therefore, any standards initially set may be an undue burden on these laboratories.

STATEMENT OF THE AMERICAN HOSPITAL ASSOCIATION, LEO J. GEHRIG, M.D., SENIOR VICE PRESIDENT

Mr. Chairman, I am Leo J. Gehrig, M.D., Senior Vice President of the American Hospital Association. Our Association represents over 6,400 health care institutions (including most of the hospitals in the country: extended and long-term care institutions, mental health facilities, and hospital schools of nursing), and over 27,000 personal members. We are pleased to have this opportunity to present our views and recommendations to the Subcommittee on Health on H.R. 10909, the Clinical Laboratory Improvement Act of 1978.

The American Hospital Association, Mr. Chairman, has consistently supported programs designed to assure safe and competent health care in hospitals and other health care institutions, including programs that contribute to the prompt availability of reliable clinical laboratory service at reasonable cost.

In our previous testimony on similar legislation, we have sought to emphasize that certain provisions would unduly and unnecessarily add to hospital costs and to the costs of government regulation. We are not aware of any broad studies which document widespread hospital laboratory fraud and abuse or which provide evidence of inferior quality of hospital laboratory services. In view of the absence of evidence of such deficiencies in hospital clinical laboratories, we believe that the bill's coverage of hospital laboratories should more adequately take into account existing quality control activities and the review and inspection programs which already are in place.

Our concern, Mr. Chairman, is that this legislation, intended to improve laboratory services, not set a rigid matrix for hospitals that will restrict the flexibility needed to provide quality services in hospitals, which vary in size, location, and scope of services. We share the concerns of this Subcommittee with regard to the issue of rising health costs and, therefore, are particularly sensitive to actions which we believe will raise hospital costs for reasons hospitals will not be able to justify. Moreover, we believe this legislation should not cause hospital and federal regulatory costs to escalate without commensurate improvements in the quality of care.

Mr. Chairman, I would like to begin our testimony by addressing briefly several areas of concern we have regarding the recognition of voluntary accrediting entities and the coordination of this legislation with the provisions of current Medicare regulations as applied to hospital clinical laboratories. I would then like to share with the Subcommittee the concern of our Association about the potential adverse effect of certain aspects of this legislation on hospital laboratory costs, particularly for laboratories located in small, rural hospitals, and the need for flexibility in the implementation of this regulatory program.

RECOGNITION OF VOLUNTARY LABORATORY ACCREDITING AGENCIES

As you know, this legislation includes amendments to Title XVIII that would require hospital clinical laboratories to be licensed as a condition of participation in Medicare. We can understand the need to coordinate various requirements and standards pertaining to clinical laboratories, but we are concerned that the role of existing voluntary inspection and accreditation programs for clinical laboratories is not adequately recognized. While H.R. 10909 does permit the Secretary to "enter into agreements with qualified public or nonprofit private entities" to determine compliance with national standards and administer proficiency tests and other examinations, this provision, in our judgment, leaves open several critical issues.

First, a determination by the Secretary of HEW that the standards of a voluntary program are equivalent does not seem to be binding on any state that has been delegated primary enforcement responsibility. For example, should the Secretary find that the review of a clinical laboratory in an accreditation survey conducted by the Joint Commission on the Accreditation of Hospitals (JCAH) is equivalent to the national standards imposed by this legislation, we do not find any language that would require delegated state programs to accept JCAH accreditation for purposes of licensure. This could, in our view, result in duplicate inspection of hospital clinical laboratories, entailing significant costs and administrative burdens.

We do not believe this is the intention of the Congress and, accordingly, we would recommend that where the Secretary has made a finding of equivalency for a voluntary program for clinical laboratories, the licensure programs of the federal or state governments be required to accept accreditation by such programs as fully meeting the conditions of licensure.

Second, H.R. 10909 authorizes the imposition of a licensure fee in an amount not to exceed $500. We believe this fee, if not prudently administered, could be a significant expense for the small, rural hospitals and their patients that must ultimately bear such expenses. Further, if such a fee is levied on laboratories which have successfully participated in an approved voluntary accreditation program, it obviously would be in addition to the fees paid to the voluntary program and could undermine continued participation in voluntary accreditation. We recommend that the licensure fee be waived for those laboratories which successfully complete the survey of an approved voluntary accreditation program, or that only a nominal fee be imposed to cover costs related to the issuance of a licensure.

Finally, we believe that the language of H.R. 10909 in section 377(a) concerning the role of private entities in the implementation of national standards for clinical laboratories could be interpreted as requiring that such private entities act as agents of the federal or state governments to enforce compliance with this legislation's requirements. The language is significantly different from existing provisions of the Medicare program wherein accreditation by the JCAH is "deemed" as sufficient evidence of a hospital's compliance with Medicare conditions of participation.

As you know, hospital participation in the activities of the JCAH is purely voluntary. In our review of the Senate committee report on S. 705 and the House Commerce Committee report on H.R. 10909, we note strong support for the recognition of voluntary accrediting programs where they have been found to apply equivalent standards for clinical laboratories. Therefore, we recommend that the language of Section 377(a) of H.R. 10909 be amended to provide that accreditation by private programs found to be equivalent by the Secretary be deemed to satisfy the requirements for licensure under this legislation.

REVISION OF MEDICARE CONDITIONS OF PARTICIPATION

As you are aware, Mr. Chairman, the Department of HEW is currently revising the standards for clinical laboratories participating in Medicare. In view of this Committee's oversight responsibilities for the program and the relationship of this activity to the legislation under consideration today, we want to bring to the Subcommittee's attention a concern we have about proposed personnel standards. Specifically, in the case of small rural hospital laboratories, we have serious reservations about a requirement that directors of clinical laboratories be on the premises at least eight hours every week.

Mr. Chairman, approximately 2,000 community hospitals in this country have fewer than 100 beds. Of this number, 75 percent are located in rural areas. Further, about 1,500 community hospitals have fewer than 50 beds and generally

operate very small laboratories. The general practice among these hospitals is that two or more share the services of a director who visits each on a scheduled and as-needed basis. Given the shortage of qualified directors and the high cost of retaining their services, it is unreasonable to expect that rural hospital laboratories will be able to guarantee the presence of a qualified director for one full day every week. Further, the limited scope and volume of tests which these small laboratories perform, coupled with the internal quality control procedures which they themselves conduct and the availability of consultations as needed, could make the presence of a highly qualified director for 8 hours every week unnecessary and uneconomical.

We cite this illustration in order to emphasize the need for flexibility and prudence in the development and implementation of a regulatory program of the magnitude proposed in H.R. 10909, and we hope that the Committee's report will include an appropriate admonition to HEW in this regard.

SCOPE OF FEDERAL PERSONNEL STANDARDS

In the last three years, the AHA has testified on this legislation on a number of occasions and, at each of the hearings, among the principal issues we have addressed have been the cost impact this bill would have on hospitals and the difficulty small hospitals may experience in attracting and retaining personnel with the requisite qualifications. These problems, in our view, would be particularly acute in small, rural hospitals. We are pleased to note that since its introduction in 1975, this legislation has been amended to give greater consideration to the unique characteristics of rural health facilities. But there are two issues which, in our opinion, have not yet been adequately addressed; and, although they are issues that do not fall within the sections of H.R. 10909 which would amend Medicare, I nevertheless would like to bring them to the attention of this Subcommitee.

Mr. Chairman, H.R. 10909 mandates the development of federal personnel standards for laboratory directors, supervisors, and technologists. In previous testimony on this legislation, the AHA has recommended that personnel standards not be mandated for laboratory personnel below the supervisory level. Although we believe that setting minimum standards for laboratory directors and supervisors can be justified, we feel that mandating requirements for laboratory personnel below that level would—particularly for rural hospitals—be costly, undesirable, and unnecessary to achieve the goals of this legislation. Many capable individuals who have no formal credentials are now performing the tasks required to provide satisfactory laboratory services, and we believe that it is desirable to allow those who are performing well to continue to provide services.

Moreover, the development of personnel standards below the supervisory level would be undesirable from the standpoint of effective manpower utilization. New technology and new techniques being developed today are changing the skills and knowledge needed by laboratory personnel. Whereas in the past certain procedures could be performed only by specially trained workers, today innovations such as automation and prepackaging of tests have altered the skill requirements for many procedures.

Finally, compliance with federal standards for nonsupervisory personnel would be costly. As the following tables illustrate, there are significant differences among hospitals in wage and salary costs, depending on types of laboratory personnel employed. Data from the Chicago Hospital Council and the American Medical Association support this point as follows:

	Lowest	Average	Highest
Hourly wage scale:[1]			
Laboratory assistant	$3.39	$3.87	$3.93
Laboratory technician (not registered)	4.10	4.96	5.79
Medical technologist	5.29	5.95	6.95
Annual salary ranges:[2]			
Clinical laboratory assistant (CLA)	6,000	7,500	10,000
Medical laboratory technician (MLT)	7,500	9,000	12,000
Cytotechnologist (CT)	8,500	10,000	14,500
Medical technologist (MT)	9,000	10,000	15,500
Specialist in blood bank technology	18,000	19,500	22,000

[1] Salary and benefit structure of Chicago area hospitals, Chicago Hospital Council, January 1977.
[2] Education for Allied Health Centers, American Medical Association, 1976.

At a time when hospitals are being criticized for rising health care costs and are engaged in a Voluntary Effort to contain costs, we must point out that unnecessary and not truly relevant personnel requirements in the laboratory would increase costs substantially without enhancing the quality of services. We therefore recommend that the personnel standards to be developed under the bill not extend below the supervisory level.

RENEWABLE WAIVER FOR RURAL HOSPITAL LABORATORIES

Mr. Chairman, inflexible personnel requirements would be felt sharply by the clinical laboratories based in small, rural hospitals. Administrators of rural hospitals who are experiencing recruitment problems tell us that they face serious difficulty in obtaining laboratory personnel because (a) there is not enough challenge in the types of tests rural laboratories perform to interest highly trained technologists; (b) rural hospital laboratories offer little opportunity for career advancement; and (c) rural communities do not offer the variety of social opportunities or entertainment often associated with life in urban areas. Thus, if rigid personnel standards are applied they could result in an inability among small hospitals to utilize even the limited scope of laboratory services they have and would thus cripple the capability of such institutions to care for their patients.

We believe these circumstances are similar to those that faced the Subcommittee in the 24-hour registered nurse coverage required under the conditions of participation in Medicare. In 1971 Rep. Omar Burleson (D-Tex.) proposed an amendment to the Medicare statute that permitted the Secretary of HEW to waive the requirement for participating hospitals to have 24-hour registered nurse staffing, provided the hospitals were making good faith efforts to achieve compliance with this requirement and provided no undue health hazards existed. This provision, enacted by Congress as an amendment to the Social Security Act in 1971 (P.L. 91–690), has been important in assuring access to needed hospital care for Medicare beneficiaries. Although initially some 600 hospitals were granted waivers under this provision, recent HEW data indicates that 36 hospitals are presently waivered. This suggests that efforts to achieve compliance with Medicare requirements will continue notwithstanding the potential for a renewable waiver. Moreover, the waiver provision permits the Secretary to recognize and deal constructively with the special problems of recruiting and retaining health professionals in many rural and often isolated areas.

Because of the difficulty which rural hospitals have in recruitment and retention of qualified personnel and the unlikely probability of significantly modifying the social, professional, and residential environment in which rural hospitals are located, the American Hospital Association recommends that a renewable waiver of personnel requirements be provided for hospitals located in isolated areas where there are shortages of qualified laboratory personnel. Consideration for award of this waiver would take into account the geographic location, volume, and type of tests that are essential to the provision of services in otherwise medically underserved areas.

We envision that utilization of such a waiver might follow much the same pattern as that of the waiver from the Medicare 24-hour nurse staffing requirement mentioned above. All rural hospitals would try to comply with the personnel requirements, and most would be successful in securing the services of qualified persons, at least for a time. But for those which would be unsuccessful in their recruitment efforts, or for those which would lose the services of qualified employees, the waiver would provide an exemption which would enable them to continue providing needed laboratory services until they were able to achieve compliance with federal requirements.

Recommendation: The American Hospital Association recommends that the new section 372(c)(2) on page 9 of H.R. 10909 be amended to read:

"(2) During the two-year period *and, upon approval by the Secretary for subsequent two-year periods* beginning on the date that national standards for clinical laboratories first take effect under subsection 371 (or in the case of a clinical laboratory which is not engaged in business in interstate commerce and which is not subject to section 103(a)(2) of the Clinical Laboratory Improvement Act of 1976, during the two-year period beginning on the date such standards prescribing qualifications for supervisory personnel or the provision of such standards prescribing qualification for technologists, or both provisions, should not apply to a clinical laboratory which:

"(A) the Secretary determines is located in a rural area (as defined by the Secretary) in which there is not a sufficient number of individuals with the qualifications prescribed by such provisions for supervisory personnel or technologist, as the case may be,

"(B) performs services solely for hospitals and licensed physicians, dentists, or podiatrists (or any combinations of such practitioners) located within such a rural area, and

"(C) provides the Secretary satisfactory assurances that it will take such actions as may be necessary to train individuals to meet such qualifications *on a continuing basis* or to employ individuals with such qualifications."

* * * * * * *

Mr. Chairman, we appreciate this opportunity to present our views and recommendations on this legislation, and we would be pleased to respond to any questions you or other members of the Subcommittee may have.

THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS,
Park Ridge, Ill., May 1, 1978.

Hon. DAN ROSTENKOWSKI,
Chairman, Subcommittee on Health,
House Committee on Ways and Means,
Washington, D.C.

DEAR CONGRESSMAN ROSTENKOWSKI: It has been brought to my attention that your Committee will conduct hearings on the Clinical Laboratory Improvement Act of 1978 on May 9 and 11, 1978. My purpose for writing to you is to express support for the Bill and make you aware of past and present concerns to the membership of the American Society of Anesthesiologists, The Society of Academic Anesthesia Chairmen, and The Society of Critical Care Medicine.

On June 14, 1977, I had the pleasure of testifying before Congressman Rogers' subcommittee on this issue. I am enclosing a copy of my prepared remarks as presented at that time.

I am pleased to inform you that Item 2, "Physician's Office Exemption", and Item 3, "Experimental Laboratories", have, in my opinion, been addressed in the rewriting of H.R. 6221 to the current H.R. 10909. The physician's office exemption provision we requested has been taken care of by redefining the clinical laboratory and the experimental laboratory section has been taken care of by a redraft of the language in the Bill.

The only area which I addressed in June of 1977 for which there has not been a specific change in the Bill is the first paragraph dealing with "Special Purpose Laboratories". However, even though the change in language that we suggested was not made in the Bill, I have reassurances from Mr. Steve Lawton, and also letters on file from Congressman Rogers, that the intent of the Bill is consistent with our position. I am confident, therefore, that his committee will write the proper language to ensure appropriate direction of limited purpose laboratories. To support my confidence, I quote a letter from Congressman Rogers to Dr. Peter Cohen, Chairman of the Department of Anesthesiology at the University of Michigan, "I am in full agreement with your position that specialized clinical laboratories which are not directed by clinical pathologists should not, as a result of clinical laboratory legislation, come under the purview of the pathology department of a hospital. You will be pleased to know that the legislation introduced by me and other members of the House Health Subcommittee, H.R. 6221, requires that standards and procedures for clinical laboratories are to vary, based upon the type of laboratory involved. I have instructed my staff to include, at the appropriate time in the Committee report which will accompany the legislation, language indicating that clinical tests which are appropriately under the supervision of departments of anesthesiology should, under the legislation, continue to be directed by personnel under the supervision of and responsible to a hospital's department of anesthesia."

I would appreciate it if in your committee report you would also express this intent in order to ensure that when the Bill is implemented it will be interpreted properly.

I also would appreciate it if this letter and its enclosures would be included in the record of the above mentioned hearings of your subcommittee. Thank you in advance for your kind consideration.

With best regards.

Sincerely yours,

JEROME H. MODELL, M.D.,
Chairman, Committee on Governmental Affairs.

Enclosure.

STATEMENT OF JEROME H. MODELL, M.D., ON BEHALF OF THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS (ASA), THE SOCIETY OF ACADEMIC ANESTHESIA CHAIRMEN (SAAC), AND THE SOCIETY OF CRITICAL CARE MEDICINE (SCCM)

I appear before you today in my role as president of the Society of Academic Anesthesia Chairmen (SAAC) to testify regarding H.R. 6221. I have been requested by Dr. Richard Ament, president of the American Society of Anesthesiologists (ASA), and by Dr. Ake Grenvik, president of the Society of Critical Care Medicine (SCCM), to represent those groups as well.

The Society of Academic Anesthesia Chairmen (SAAC) is an organization comprised of the chairpersons of departments of anesthesiology in all the medical schools of the United States. Thus, the members of SAAC represent the entire community of anesthesiologists and related scientists who reside in medical school departments of anesthesiology and are responsible for clinical care, research, and education of physicians, nurses, and paramedical personnel within their area of expertise in those medical schools. The second group I represent, the American Society of Anesthesiologists (ASA), is a national medical organization of physicians having approximately 11,000 active members engaged in the practice of anesthesiology. The third group, the Society of Critical Care Medicine (SCCM), is oriented specifically to the care of the critically ill patient. Its membership consists of persons having an interest and demonstrated expertise in this field and at present numbers approximately 650.

In concept and in all major respects, SAAC, ASA, and SCCM favor adoption of H.R. 6221 as representing an intelligent step forward in the improvement of quality control in the clinical laboratories of the United States, and in the containment of costs associated with those laboratories. In the interest of proper, effective, and more economical patient, care, however, we have three recommendations that we feel would improve and clarify the Bill.

1. *Special-Purpose Laboratories.* Subsection 353(b) of the Bill requires that the Secretary of Health, Education, and Welfare promulgate national standards for all clinical laboratories, which standards will include requirements relating to quality control, facilities, period proficiency tests, and training and qualifications of laboratory personnel. The definition of clinical laboratories under subsection 353(a) is, of course, sufficiently broad to cover virtually any laboratory concerned with patient care, and we believe would be most commonly understood to apply to the multipurpose clinical laboratories found both inside and outside hospitals.

In most major hospitals, however, there exists a number of single- or limited-purpose laboratories and highly specialized laboratories, the function or purpose of which is normally to analyze some particular body function or functions required immediately in connection with patient care. An excellent example of such a laboratory is a blood-gas laboratory, the purpose of which is to analyze a patient's blood for determining its relative acidity, its oxygen and carbon dioxide tensions, and related parameters. Although quality control is absolutely essential in such a laboratory, qualified persons can be taught to perform the tests, even though such persons do not have a background in the entire field of medical technology. It should be obvious that learning a limited number of techniques requires far less formal training than becoming proficient in analyzing the many parameters that might be found in a central or multi-purpose hospital laboratory.

A second example is the acute intensive care laboratory. Its purpose, in addition to analyzing blood for acidity and oxygen and carbon dioxide tensions, is to perform emergency tests required for the moment-to-moment care of critically ill patients. The speed necessary for obtaining such data usually precludes using the mass-produced or automated testing techniques common to most multi-pur-

pose laboratories. It is imperative that the data be accurate and available immediately, since the care of the critically ill patient must frequently be changed on a moment-to-moment basis if he is to survive. Of further importance is the fact that some parameters, such as the oxygen tension of blood, can change rapidly if there is any significant delay between the time of drawing the sample and the time that the oxygen tension is actually determined by suitable equipment. Thus, proximity of the laboratory to the areas of highest usage rate and recognition of the need for working rapidly by the persons collecting, transporting, and analyzing these blood samples is essential. This can best be assured by placing such a laboratory immediately adjacent to high usage areas, such as the intensive care unit or operating room, and by making the medical director of that unit responsible for its direction.

With reference to laboratories of these types, SAAC, ASA, and SCCM are concerned that upon passage of H.R. 6221, the Secretary may promulgate national standards entirely appropriate to a centralized multi-purpose hospital or independent laboratory, but which are unrealistic or unnecessary with respect to the single- or limited-purpose laboratory, or which render the cost of operating such a laboratory undesirable from the point of view of the patient, and ultimately from the point of view of the Federal Government as one of the principal payers of health care costs.

SAAC, ASA, and SCCM are aware of the provisions of subparagraph 353(b)(2)(C), which *permit* different standards depending upon the type of laboratory and the purposes it serves. It is suggested, however, that merely to include permissive language in this subparagraph is inappropriate, and that H.R. 6221 should *mandate* different standards depending upon the nature of the laboratory involved. This can be accomplished by changing the word "may" to "shall" in this section of the Bill, as it appears on page 7, as follows:

"(C) Standards prescribed under subparagraph (A) for clinical laboratories [may] *shall* vary on the basis of the tests or other procedures or services performed by such laboratories or the purposes for which such tests, procedures, or services are performed.

Such a mandate should also be explained appropriately in the report of the Committee, possibly in the following terms:

The Commiteee recognizes that appropriate national standards for clinical laboratories will vary, depending upon the type of function or functions to be performed by the various laboratories in question. Standards appropriate to a central hospital laboratory or independent laboratory created and operated to perform a variety of procedures or services will not be appropriate to single- or limited-function laboratories created and operated to perform tests in connection with a particular kind of patient care. Examples of the latter types of laboratories, normally located close to the actual site of patient care and normally operated by a licensed physician who may also be the medical director of the hospital's unit for that type of care.

2. *Physician's Office Exemption.* As you know, H.R. 6221 presently contains an exemption, under subparagraph 353(c)(2)(D), for clinical laboratories located in the office of a licensed physician. As you are also aware, the operating room, obstetrical suite, recovery room, and intensive care unit of a hospital are, for all practical purposes, the "office" of an anesthesiologist. Reference to a physician's "office" under the current Medicare statute in connection with services incident to a physician's service has been construed by the Bureau of Health Insurance, in the case of an anesthesiologist, to relate to the hospital setting in which he performs his medical services. Similar reasoning would suggest that the "office" of the intensivist can properly be the hospital's intensive care unit. SAAC, ASA, and SCCM believe there would be considerable merit in clarifying this subparagraph of H.R. 6221, in order to make clear that the exemptions apply to the "office" of an anesthesiologist and intensivist. We would thus recommend that subsection (1) of subparagraph (D) be changed to read as follows, with a parallel change being made in subsection (ii):

"(D) (i) The national standards for clinical laboratories shall not apply to any clinical laboratory—

"(I) which is located in the office *or ordinary place of medical practice* of, and operated by, a licensed physician, dentist, or podiatrist, or a group of such practitioners, and

"(II) in which the only tests and procedures which are performed are tests or procedures performed by such a practitioner [in connection with] *as an adjunct to* the treatment of his patients.

SAAC, ASA, and SCCM believe that this amendment would represent an appropriate clarification of the "office" clinical laboratory without any way detracting from the basic purpose of H.R. 6221.

Should the rationale and importance of such designation be unfamiliar to any Committee member, I will explain further. The anesthesiologist and the intensivist, in the routine care of their patients, must analyze biophysical and biochemical data on a moment-to-moment basis and, based on this data, must apply the necessary therapy. Some examples would include, among others, continuous beat-by-beat function of the heart, breath-by-breath analysis of exhaled gas, beat-by-beat analysis of the configuration of arterial pressure waves, constant monitoring of the inspired oxygen concentration, and determinations of cardiac output. These tests are all done at the patient's bedside or operating room table, as appropriate. The nature of the tests and the speed with which therapy must be applied if changes occur precludes either transmitting the data to any other "central laboratory" or consulting with any other "laboratory director". Furthermore, feeding this information into a central area and having an analysis returned would necessitate a very expensive system of telemetry and computerization that is at the present time neither available nor necessary in most hospitals.

Second, we suggest changing the words "in connection with" to the phrase "as an adjunct to" so that it would be possible to exempt as a physician's "office" that area and those physicians that directly prescribe therapy on a moment-to-moment basis, as opposed to those who use the tests for diagnosis only and then refer patients to other physicians for therapy. With this alteration in language, we believe it would be possible to accomplish our goal of continued excellence in patient care without creating as an "office exemption" the offices and laboratories of all physicians.

We believe that the Committee report should contain language making the previously mentioned points. Such a modification would have the effect of assuring that the anesthesiologist and the intensivist could monitor their patients on a moment-to-moment basis, through the use of analytical equipment located in the operating room, recovery room, or intensive care unit, without the necessity of being forced to register themselves as a "clinical laboratory" under H.R. 6221. This would permit them to make the necessary adjustments in the care of their patients. One suggestion for such language would be the following:

The Committee recognizes that for some physicians, such as the anesthesiologist and intensivist, the "office" is a special area within a hospital. In the case of the anesthesiologist, this would be the operating room, the obstetric suite, the recovery room, and the intensive care unit; in the case of the intensivist, it would be the intensive care unit. It is essential that these physicians be permitted to analyze biophysical and biochemical data relating to their patient on a moment-to-moment basis in order to alter therapy as appropriate. The Committee recognizes that this is essential and, therefore, wishes the term "office" to be expanded to include "the ordinary place of medical practice of" the physician whenever the tests performed are used as an adjunct to the treatment of his patient.

3. *Experimental laboratories.* Unlike the Senate version of the Clinical Laboratories Improvement Act, H.R. 6221 states that the Secretary may exempt from the national standards for clinical laboratories any laboratory in which the only tests or procedures which are performed are tests or procedures for research (other than research to determine the course of treatment for an individual patient) section 353(2)(iv). The Senate version permits exemption, on application, for research laboratories engaged "*primarily*" in research.

SAAC, ASA, and SCCM feel that there are certain types of tests which, because of their complexity, rarity of need and, therefore, relatively high cost of maintaining test facilities, can be performed only in laboratories that are maintained primarily for purposes of research. The "individual patient" exemption contained in H.R. 6221 will not, it is believed, permit research laboratories offering such a rare test for the benefit of any patient to obtain exemption from the national standards requirements. If this interpretation is correct, H.R. 6221 will preclude the physician from confirming diagnosis of rare or uncommon diseases for which the appropriate tests are not available in most laboratories. It is well known, for example, that the definitive tests necessary to diagnose such rare disorders as malignant hyperthermia and atypical pseudocholinesterase are available in only a handful of research laboratories in the United States. It is essential that our patients and their physicians be permitted to take advantage of such laboratories.

On the other hand, we understand the concern of the Committee that merely changing the language to coincide with the Senate version of the Bill might lead to abuse. For example, a laboratory that is operated 51 percent for research purposes and 49 percent for "routine" clinical work could be exempt and, therefore, use this loophole to fund their research laboratory through payment for clinical tests. This would defeat the purpose of H.R. 6221. If the Committee wishes to adopt the language in the Senate version of the Bill, we believe that this loophole could be plugged by appropriate language in the Committee report, such as the following:

The Committee recognizes the fact that there are some laboratory tests that, because of their complexity and rarity of need, can be performed economically only in laboratories that are maintained primarily for purposes of research. The Committee wishes to exempt, on application, those tests within such research laboratories, since they fulfill a national need that is not available through routine channels. The Committee cautions the Secretary, however, that it does not condone a situation in which a laboratory, normally used primarily for research, performs a significant number of "routine" laboratory tests, thereby using its research designation to avoid conforming to the law.

An alternate approach would be to amend H.R. 6221 section 353(2)(D)(iv) found on lines 19–24, page 12, in the following terms:

"(iv) The Secretary shall, upon application, exempt, on such terms and conditions as may be appropriate, from the national standards for clinical laboratories any laboratory in which the only tests or procedures which are performed are tests or procedures for research *or for the analysis or diagnosis of rare disorders* [(other than research to determine the course of treatment for an individual patient)].

SUMMARY

In concept and in all major aspects, SAAC, ASA, and SCCM favor the adoption of H.R. 6221 as representing an intelligent step forward in the improvement of quality control in the clinical laboratories of the United States and in the containment of costs associated with these laboratories. This statement is made assuming the following clarifications are adopted:

1. That the Secretary *shall* promulgate national standards that recognize the different natures of laboratories created to serve specific purposes.
2. That the "office" of the anesthesiologist and the intensivist includes "his ordinary place of medical practice", namely, the operating room, obstetric suite, recovery room, and intensive care unit, as appropriate.
3. That extremely complex or rare tests performed in research laboratories which perform such tests for the diagnosis of rare disorders should be exempted, on application, by the Secretary, thus permitting the results of such tests to be used in patient care.

I appreciate the opportunity to share my views, on behalf of SAAC, ASA, and SCCM, with you. Thank you.

STATEMENT OF THE AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS

The American Society of Clinical Pathologists is a non-profit, educational and scientific medical specialty society representing approximately 6,500 medical doctors who are board certified pathologists practicing laboratory medicine and representing 17,000 other medical laboratory professionals.

Our members practice in a wide variety of clinical laboratory environments: hospitals, universities, independent laboratories, military and veterans' hospitals and federal, state, and local government facilities.

We are vitally concerned with the quality of health care in the USA and are committed to upholding the highest standards of medical practice in the clinical laboratory.

Laboratory services throughout the United States are the finest in the world. They are constantly being improved voluntarily through the dedication and hard work of many individuals and professional organizations.

We oppose fraudulent activity in any type of clinical laboratory and want to do anything possible to ensure that all clinical laboratories are of high quality and conduct their work with honesty and integrity. We commend this committee for its interest and concern about these practices.

We offer the following specific comments on H.R. 10909:

1. Proficiency Testing:

An amendment to Section 371 provides for required on-site proficiency testing and optional blind proficiency testing. A requirement for on-site proficiency testing is unrealistic and impractical because of the tremendous cost, technical problems in producing the samples and the skilled personnel required to make such a program a success. This will considerably increase expense and will not improve patient care.

Proficiency testing is a vital part of any laboratory quality control program and is absolutely necessary in all laboratories. The existing recognized and equivalent proficiency testing programs, both private and state, should be expanded and strengthened. This could be very effective with little additional expenditure.

Similar problems are associated with a blind proficiency testing program. The cost would be prohibitive; further, it would be virtually impossible to develop a system whereby "blind" (unidentified or falsely identified) specimens could be submitted to a laboratory without laboratory personnel identifying them as test samples.

2. Exemption of Specialized Laboratories: Section 372(c)(5) provides an exemption from national standards for highly specialized clinical laboratories "engaged exclusively in the assessment of cardiac or pulmonary function."

All patients deserve laboratory test results of high quality. Laboratory services should not be exempted from national standards on the basis of the location in which they are performed, and/or the procedures performed. Patients in need of cardiac-pulmonary function testing, especially as it relates to active or proposed therapeutic procedures, often require procedures which are of a critical nature. They should receive the highest quality of work attainable.

These laboratories should meet the same standards as those imposed on the central laboratory in the hospital.

3. Competitive Bidding for Medicaid Lab Services: Section 203(a)(1) would allow competitive bidding arrangements for the obtaining of laboratory services provided to Medicaid patients.

Cost of services is not an index of quality. It is in this area of the relationship of cost to the care or service provided that opportunities for fraudulent activity have been discovered in the past. In a system of competitive bidding the *quality* of the laboratory services provided to Medicaid patients would take second place to the *cost* of those services.

Costs for laboratory tests vary considerably. For example, costs are higher to provide 24 hour a day laboratory test service for critically ill hospitalized inpatients. Lower costs are required to provide batches of laboratory tests performed on mildly ill outpatients.

Competitive bidding is not the appropriate method for obtaining quality laboratory services. This section of the bill should be deleted.

4. The ASCP wishes to vigorously support Section 377 which provides the opportunity for private non-profit entities to enter into agreements with the Secretary or with a state which has primary enforcement responsibility to perform such services as inspections, proficiency testing, and the examination of laboratory personnel. There are organizations in the private sector, such as the American Society of Clinical Pathologists and the College of American Pathologists, which have long experience and extensive knowledge in one or more of these areas. This expertise should be utilized as an alternative or a complement to federal and state programs.

The ASCP appreciates the opportunity to comment on H.R. 10909, The Clinical Laboratory Improvement Act of 1978.

AMERICAN SOCIETY OF INTERNAL MEDICINE,
San Francisco, Calif., May 10, 1978.

Congressman DAN ROSTENKOWSKI,
U.S. House of Representatives, Rayburn House Office Building,
Washington, D.C.

DEAR CONGRESSMAN ROSTENKOWSKI: It was a pleasure and an honor to have testified before you and the House Ways and Means Health Subcommittee yesterday morning on issues relating to H.R. 10909, "The Clinical Laboratory Improvement Act of 1978". Due to the time constraints placed on our oral testimony, I would like to present, for the record, the views of the American Society of Internal Medicine on an additional matter of importance, the Competitive Bidding provisions of the legislation.

Section 203(a) of the bill would amend Section 1902(a)(23) of the Social Security Act to permit states to purchase, for a three year period, laboratory services for Medicaid recipients through a competitive bidding process. We foresee this creating several problems that negate, in our opinion, any cost savings that might accrue through competitive bidding.

Because the services provided by different laboratories are rarely comparable, it would be difficult, if not impossible, to develop criteria for awarding bids to the lab that offers the best quality service at the lowest price. Instead, because of overriding cost considerations, we believe bids would be awarded to labs offering inferior services, and Medicaid patients would receive lower quality care. As ASIM noted in its previous testimony, this undercuts the very objective of the Medicaid law by establishing a separate system of laboratory service delivery to the poor.

Contracting with a limited number of laboratories would also unduly restrict access of Medicaid patients to lab services. Because physicians' office labs would be unlikely to win contracts through the competitive bidding process, physicians would be unable to perform lab tests for their Medicaid patients. If they continue to collect specimens, some patients would be required to make a return trip to the office to learn of the results and prescribed treatment. However, because Medicaid payment for collecting specimens often makes it uneconomical to do this alone, some physicians would be forced to send patients to independent or hospital labs to have specimens collected. Medicaid patients, who are generally less mobile than the rest of the population, would often be required to travel farther distances to find a lab under contract.

Emergencies and other situations sometimes require that test results be obtained immediately and this would not always be possible from the lab under contract. So, apparently, regulations will have to be issued allowing for reimbursement to non-contract labs under certain circumstances and further complicating both reimbursement and claims review.

Collectively, independent labs already represent one of the most competitive components of the medical care system. This competition results in improved services and fairly stable prices. However, under competitive bidding, most contracts would presumably go to high-volume, automated labs. And physicians forced to send specimens for Medicaid patients to the labs might well find it convenient to use the same labs for non-Medicaid patients. This would force many small labs out of business, destroy the competitive balance, and ultimately result in higher prices and fewer incentives to develop new processes.

We believe that physicians are in the best position to select the laboratory that will provide the best services to each patient. To mandate separate lab service for Medicaid patients can only serve to further remove them from the mainstream of medical care delivery, making them "second class" patients.

Accordingly, the American Society of Internal Medicine urges that the competitive bidding provision be eliminated from H.R. 10909.

If I can provide you with any further information or assistance, please let me know.

Sincerely,

T. Reginald Harris, M.D.
Board of Trustees, ASIM.

Association of American Medical Colleges,
Washington, D.C., May 10, 1978.

Representative Dan Rostenkowski,
Chairman, Subcommittee on Health, Committee on Ways and Means,
Washington, D.C.

Dear Mr. Chairman: In accordance with the Subcommittee's April 21st, 1978, request for testimony, the Association of American Medical Colleges (AAMC) is pleased to have this opportunity to comment for the record on the Clinical Laboratory Improvement Act of 1978, H.R. 10909. In addition to representing all of the nation's medical schools and sixty-three academic societies, the Association's Council of Teaching Hospitals includes over four hundred of the nation's major teaching hospitals. These hospitals: account for over sixteen percent of the admissions and approximately twenty percent of the ambulatory care service provided by non-federal, short term hospitals; provide a comprehensive range of patient care services, including the most complex tertiary services; and

are responsible for a majority of the nation's graduate medical education programs. Thus, the laboratory standards and operational requirements proposed in the Clinical Laboratory Improvement Act are of a direct interest and a vital concern to the Association's members.

The Association of American Medical Colleges is seriously concerned about the impact that H.R. 10909 may have on the Medicare program, on other third party payers, and on patients who privately pay for health care services. During the last year, this Subcommittee has devoted a substantial amount of its efforts to hearings and deliberations on hospital cost containment. The personnel credentialing provisions of H.R. 10909 would have precisely the opposite effect by restricting the ability of hospital management to contribute to national efforts to contain health care costs and by inflating hospital and health care costs.

The Association of American Medical Colleges agrees that, in order to assure accuracy and quality in clinical tests, clinical laboratories should be required to maintain appropriate quality control programs, records, equipment and facilities, and to perform satisfactorily in periodic proficiency testing. Therefore, the Association strongly supports the inclusion of those provisions in this Act. The AAMC believes, however, that the credentialing of laboratory personnel below the level of director and supervisor will not be an effective method of assuring the quality and validity of clinical tests. The rationale for this conclusion is based on the following considerations.

The extent to which the validity of laboratory results is dependent upon the credentials of laboratory personnel is presently unknown; the available evidence, anecdotal in character, both supports and denies the relationship and renders any conclusion questionable. This book of knowledge of a relationship between performance and personnel credentialing is even recognized in Section 102 of the bill which requires the Secretary of HEW to investigate the question. Under these circumstances the Association believes it is inappropriate to require or permit the Secretary of HEW to promulgate credentials for laboratory personnel.

Moreover, personnel credentialing imposes artificial rigidities and inflexibilities on the number and types of laboratory personnel employed and on the tasks assigned them. These rigidities inhibit efforts to improve laboratory productivity, increase necessary personnel requirements, stimulate "featherbedding", and constrain the introduction of new procedures requiring skills not learned by those with established credentials. In a recent study of the *Employment Impact of Health Policy Developments*, published by the National Commission for Manpower Policy, Professors Rashi Fein and Christine Bishop make the following recommendation: "As growth in hospital employment lessens, it will be necessary for public authorities to intervene more actively to alter the credentialing and certification process for various health occupations. The cost of inflexibility is always high. It is likely to be even higher in a slow-growth situation. Special attention must be paid to these matters . . . Health policy makers should be aware of the impact of their proclivity to equate input quality with output quality, and attempts should be made to encourage more flexible staffing patterns for health providers."

Hospitals are extremely complex social institutions requiring the coordinated activity of many occupations to function effectively. Hospital services and departments must work to complement and supplement one another if high quality patient care is to be maintained. The credentialing provisions of the present bill threatens to fragment the hospital by regulation and licensure on a service by service, department by department basis, beginning with the laboratory. While the intent of the legislation is the improvement of laboratory services, its personnel credentialing provisions would probably reduce the overall effectivenss of the hospital. Hospitals are production systems whose functioning would be hampered by rigid personnel credentialing which focuses on inputs and organization rather than output. The Association, therefore, strongly suggests that this Subcommittee work to ensure hospital quality with programs aimed at institutional licensure and quality, not with programs aimed at departmental and personnel licensure.

While the benefits of credentialing would appear to be small, the cost of complying with credentialing under this Act will be significant. At a time when the public and government officials are demanding increased efficiency and effectiveness in the expenditure of funds for health care services, the Association believes that the Congress should not in this legislation force hospital laboratories to comply with provisions which markedly increase the costs of operation without a concommitant increase in the reliability and accuracy of clinical laboratory tests.

In summary, the Association strongly supports the inclusion of the provision requiring clinical laboratories to maintain appropriate quality control programs, records, equipment, and facilities and to perform satisfactorily in periodic proficiency testing; however, the AAMC opposes the credentialing of laboratory personnel below the level of directors and supervisors in clinical laboratories.

Sincerely,

JOHN F. SHERMAN, Ph. D., *Vice President.*

CONGRESS OF THE UNITED STATES,
HOUSE OF REPRESENTATIVES,
Washington, D.C.

Hon. DAN ROSTENKOWSKI,
Chairman, Health Subcommittee,
House Ways and Means Committee,
Washington, D.C.

DEAR MR. CHAIRMAN: Please find enclosed a copy of a communication received from Mr. Gordon Russell, Administrator of the Hi-Plains Hospital, located at 203 West Fourth Street in Hale Center, Texas 79041, for inclusion in the record in connection with H. R. 10909, the Clinical Laboratory Improvement Act of 1978.

Your assistance in this regard will be deeply appreciated and with good wishes, I remain

Sincerely yours,

OMAR BURLESON,
Member of Congress.

Enclosure.

HI-PLAINS HOSPITAL,
Hale Center, Tex., May 11, 1978.

Hon. OMAR BURLESON,
U.S. House of Representatives,
Rayburn House Office Building,
Washington, D.C.

DEAR MR. BURLESON: The small rural hospitals in this nation and the many communities and citizens who depend on these institutions for their health care are indebted to you for your insight and many efforts in their behalf. The Burleson Amendment allowing for a variation in nursing staffs has been, life-giving to many rural hospitals and the patients they serve. Further, hospitals have done their level best to comply with the requirements. I feel sure that you are aware of yet another threat to these same hospitals. I am referring to H.R. 10909 on clinical laboratories.

I began my career in health care following graduation from the University of Oklahoma School of Medical Technology. While later transferring to Administration I still have an intense interest in the field, possibly more than most Administrators.

Even though there is a total shortage of trained medical technologists, this shortage is specially acute in the rural hospital because of the difficulties we face in getting young single people to move to these communities. We must usually rely upon ladies whose husbands' jobs bring them to our community and they then work for us, or we must look for trained men who will move with their families to our community. Trained men are very hard to find even though we are willing to pay higher salaries to bring them to smaller communities. Many times we will find one trained technologist, then that technologist and our medical staff will train someone locally to work in our laboratory with the one technologist. These people are well trained and well supervised for the functions that they perform. I know from personal experience that these locally trained people become very proficient in the work that they do, but would not have the academic background, or training, or exposure to work not performed in that particular laboratory, to pass a national standards examination; and the quality of work for those tests performed in that institution can be unimpeachable yet they could not qualify under H.R. 10909. Under H.R. 10909 there would be qualifications for a director, supervisor, and technologists. Questions arise as to what these qualifications will be in actual practice and which one would apply to a one person laboratory.

In talking with Mr. Ken Scott, Medical Laboratory Consultant for the Texas State Department of Health, he says that improvements in clinical laboratories have been made in the last five years, but that he can see problems in rural hospitals if H.R. 10909 were passed. He feels, as I do, that a Director of Laboratories would be a requirement and that if present standards were applied this would be a medical doctor who would have four years' experience in laboratory work and spend eight hours per week in that laboratory, or it might be a technologist with a Ph.D., or maybe a Master's, with considerable experience. This type of requirement would just be unattainable for many of us.

We are concerned with cost containment, the burden of our State licensure plus the license required in Sec. 373(a) with a fee of up to $500 is not only double licensing for hospitals, but would be a cost that small rural hospitals can ill afford. This licensure fee, the cost of additional inspections, and the cost of quality and proficiency testing would really be noticed when spread over only thirty or forty beds in our small rural hospitals.

In a large institution where there are a number of people in the lab department, one or two resignations would not affect the license. In my lab, one resignation, if H.R. 10909 were in effect, would bring me out of compliance, if our laboratory would not be permitted to function it would cripple the work of our entire hospital. This sort of problem must be anticipated and provided for, otherwise, patients in small communities may be needlessly denied access to health care.

Many of us in small rural hospitals have real difficulty now with laboratory staffing. Extremely high salaries will not solve this problem. There is a real shortage in the rural area and this is further complicated by a general feeling that the current regulatory tendency goes against rural facilities. It seems vital to the life of our small rural hospitals to have something like the Burleson Amendment or other relief from H.R. 10909 if it is to be enacted.

Congressmen, I understand that you have hearings on this bill, will you include my letter in the record.

We thank you for your interest and help in providing health care to rural patients.

Sincerely,

GORDON RUSSELL, *Administrator.*

JOINT COMMISSION ON ACCREDITATION OF HOSPITALS,
Chicago, Ill., May 11, 1978.

Hon. DAN ROSTENKOWSKI,
Chairman, Subcommittee on Health,
House Committee on Ways and Means,
Washington, D.C.

DEAR MR CHAIRMAN: You will find enclosed with this letter a statement of the Joint Commission on Accreditation of Hospitals, (JCAH) on H.R. 10909, the Clinical Laboratory Improvement Act of 1978.

We respectfully request that this statement be included in the hearing record of your subcommittee on this proposed legislation.

You will note from the enclosed statement that the JCAH has three major concerns with the present construction of H.R. 10909, namely:

There are no provisions for a variable laboratory licensure fee which would recognize a clinical laboratory's participation in a recognized qualified voluntary laboratory accreditation/certification program;

The bill would seem to require qualified public and nonprofit private laboratory accreditation/certification entities to become the government's agent for laboratory certification purposes (thus destroying voluntarism in this area); and

States granted primary enforcement responsibility would be allowed to inspect clinical laboratories in spite of a prior secretarial finding that such laboratories participating in qualified voluntary accreditation programs meet Federal standards.

As you can see our concerns all relate to what we perceive to be disincentives for perpetuation of qualified voluntary programs of laboratory accreditation/certification. We seek your assistance to improve this legislation in this regard.

Thank you for your kind attention to this matter.

Sincerely yours,

JOHN E. AFFELDT, M.D., *President.*

Enclosure.

STATEMENT OF THE JOINT COMMISSION ON ACCREDITATION OF HOSPITALS

Mr. Chairman, I am John E. Affeldt, M.D., President of the Joint Commission on Accreditation of Hospitals (JCAH). I am pleased to have this opportunity to present the views and recommendations of the Joint Commission to the Subcommittee on Health on H.R. 10909, the Clinical Laboratory Improvement Act of 1978.

JCAH/HISTORICAL BACKGROUND

Before addressing myself to this legislation, I would like to present background information about JCAH. In 1951 the American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association (which withdrew in 1959 to participate in its own national hospital accreditation program) joined with the American College of Surgeons to form the Joint Commission on Accreditation of Hospitals. The JCAH was incorporated in Illinois as a not-for-profit corporation.

As stated in Article I of its Bylaws, the purposes of JCAH are:

(1) to establish standards for the operation of hospitals and other health-related facilities and services;

(2) to conduct survey and accreditation programs that will encourage members of the health professions, hospitals, and other health-related facilities and services voluntarily to

(A) promote high quality of care in all aspects in order to give patients the optimum benefits that medical science has to offer,

(B) apply certain basic principles of physical plant safety and maintenance, and of organization and administration of function for efficient care of the patient,

(C) maintain the essential services in the facilities through coordinated effort of the organized staffs and the governing bodies of the facilities;

(3) to recognize compliance with standards by issuance of certificates of accreditation;

(4) to conduct programs of education and research and publish the results thereof, which will further the other purposes of the corporation, and to accept grants, gifts, bequests, and devises in support of the purposes of the corporation; and

(5) to assume such other responsibilities and to conduct such other activities as are compatible with the operation of such standard-setting, survey and accreditation programs.

This voluntary approach to quality assurance is unique to the United States and Canada. Other countries have approached quality assurance through government regulation. Whereas, in this country health providers took the initiative to use the voluntary approach, which has resulted in an effective system of coordination between the public and private sectors.

ROLE OF JCAH

In addition to its Hospital Accreditation Program, the JCAH also establishes standards and offers voluntary accreditation programs throughout the United States for adult psychiatric facilities, children's and adolescents' psychiatric facilities, drug abuse treatment and rehabilitation programs, alcoholism treatment and rehabilitation programs, community mental health services, long term care facilities, services for mentally retarded and other developmentally disabled persons, and ambulatory health care organizations. Collectively the accreditation programs of the Joint Commission survey over 4,500 facilities, services, and programs in the course of a year, and approximately 7,300 facilities, services and programs currently hold JCAH accreditation. Represented in this statistic are over 70% of the hospitals in the United States.

The Joint Commission conceives its role, not as an inspector or judge, but as an evaluator, consultant, and educator. Its function is to help hospitals (and health related services) to identify both their strengths and weaknesses in regard to JCAH standards and to provide guidelines for improvement through consultation and education. It should be recognized that JCAH, rather than directly involving itself in the evaluation of patient care and services, fixes the responsibility for performance of these functions with the hospital and its organized medical staff. The accreditation process of JCAH is a significant mechanism through which providers of health care and related human services have been effectively motivated through voluntary professional efforts to provide higher levels of quality and service.

HOSPITAL ACCREDITATION PROGRAM STANDARDS

The JCAH standards for hospital accreditation as contained in the *Accreditation Manual for Hospitals*, 1978 edition have a long history of development. The first "Minimum Standard for Hospitals" was issued by the American College of Surgeons (ACS) in 1917. During the following 35 years ACS conducted a Hospital Standardization Program which caused a natural evolution in hospital standards. In 1952 when the JCAH survey program was implemented these minimum standards of the ACS program were utilized.

The adopted minimum standards were revised six times by the JCAH Board of Commissioners between 1953 and 1965. Then in August 1966, the Board of Commissioners voted "to review, re-evaluate, and rewrite the hospital accreditation standards and their supplemental interpretations to raise and strengthen the standards from a level of minimum essential to the level of optimal achievable and to assure their suitability to the modern state of the art.

Consequently, the standards underwent extensive revision, resulting in the 1970 edition, called, for the first time, the *Accreditation Manual for Hospitals* (*AM*). Since then, the *Manual* has undergone continuous review and revision to keep abreast of the state of the art.

Please note that all references to sections of H.R. 10909 which follow refer to the proposed sectional amendments to the Public Health Service Act.

CLINICAL LABORATORY LICENSURE

Mr. Chairman, the JCAH fully supports the purposes of H.R. 10909. We are not, however, persuaded that Federal licensure of clinical laboratories is the most economical method of improving clinical laboratory standards. We believe the objectives of this bill are on their way to achievement by the Department of Health, Education and Welfare under the existing authority of Sec. 1861(s)(11) of the Social Security Act and Sec. 5(a) of the Clinical Laboratory Improvement Act of 1967. In other words the Department currently has authority to set the standards that would be imposed by this legislation and is doing so. Further, we note that the cost estimates for this legislation as presented in the Report of the Committee on Interstate and Foreign Commerce do not include funds that would be used under the Social Security Act to inspect medicare and medicaid laboratories, and, in our view, this cost could well be substantial.

RECOMMENDATIONS

That your subcommittee consider whether the additional federal costs associated with administration of a federal licensure program for clinical laboratories will yield a benefit which clearly exceeds similar benefits achievable under existing legislation.

That if your committee perceives that this legislation significantly improves the Social Security Act with respect to clinical laboratory services, you consider the advantages of adopting only Title XVIII and Title XIX amendments exclusive of the Federal or State licensure provisions.

REDUNDANT INSPECTIONS

Mr. Chairman, this subcommittee has historically demonstrated sensitivity to the costs of government programs and in this connection has supported voluntary programs designed to assure provider qualification for participation in governmental programs.

As you know Section 1865 of the Social Security Act provides that hospitals accredited by the JCAH are deemed to meet the requirements for participation in the medicare program except for utilization review and institutional planning. Section 377(a)(1) of H.R. 10909 would also clearly allow the Secretary, and any State which has been granted primary enforcement responsibility, to find that clinical laboratories in hospitals accredited by the JCAH qualify for licensure under this Act. Although we certainly support this provision, we believe your subcommittee should have at least two concerns with respect to it.

The first concern is that states granted primary enforcement responsibility would be empowered to conduct inspections of clinical laboratories participating in voluntary accreditation programs recognized by the Secretary. Permit me to elaborate. As stated earlier, the role of the JCAH is to encourage safe and com-

petent health care in hospitals and other health care institutions, including the timely provision of reliable clinical laboratory services. JCAH standards undergo continuous review and revision. In this connection our Board of Commissioners adopted changes in our Hospital Standards for Functional Safety and Sanitation, Social Work, Special Care Units, Respiratory Care, Dietetic Services, Home Care Services and, of particular interest to this subcommittee, Pathology and Medical Laboratory Services, at its April 8, 1978 meeting. We are confident that the Department of Health, Education and Welfare will find that our newly adopted Pathology and Medical Laboratory Service Standards are equivalent to the new revised standards in this area in the process of adoption by the Department as a condition for participation in Medicare. Incidentally, these new Departmental standards are equivalent to those imposed on interstate laboratories under the Clinical Laboratory Improvement Act of 1967. We are similarly convinced that these standards will not differ significantly from standards which may ultimately be promulgated under this proposed legislation. It appears to us that H.R. 10909 may allow the Secretary to make a finding under Sec. 1865 of the Social Security Act and Sec. 377 of the proposed legislation that clinical laboratories in hospitals accredited by the JCAH meet Federal standards promulgated under Sec. 371 of the Act. Nevertheless, it also appears that, subsequently, no State granted primary enforcement responsibility would be bound by such a finding. We believe this means that a State would be allowed to conduct its own duplicative hospital laboratory inspection program despite a Secretarial finding that a qualified public or nonprofit private entity, such as the JCAH, is making inspections and accrediting hospitals with integral clinical laboratories using standards at least equivalent to those promulgated under this legislation. Considering the number of letters we receive from hospitals concerning the costly and time-consuming nature of redundant inspections, we cannot imagine that you and your staff are not deluged with similar epistles. We believe this bill can be improved in this regard.

RECOMMENDATIONS

That Section 374 be expanded to require that States as a condition of being delegated primary enforcement responsibility be required to recognize existing Secretarial agreements or findings executed under Sec. 377(a).

The second concern, although related, is broader than the first. As you know, the JCAH accredits hospitals, not distinct parts thereof. We are concerned that hospital clinical laboratory services are being singled out for separate regulatory attention apart from all other services in a hospital. We submit that it is undesirable to develop fragmented regulatory mechanisms for each hospital service. Such activity would inevitably increase the cost of providing health services and subject hospitals to even more inspections. We believe you may be able to make a very constructive change in this legislation aimed at discouraging fragmentation and encouraging efficiency and voluntarism in this area. It is in this vein that we make the following recommendations.

RECOMMENDATIONS

Retain the requirement that clinical laboratories participating in medicare meet the standards promulgated under Section 371 but amend H.R. 10909 to provide that qualification for participation in medicare provides automatic qualification for Federal licensure.

LICENSURE FEES

A physical examination would ordinarily be incomplete if the practitioner did not check his patient's cardiovascular system. In the same fashion an accreditation survey of a hospital would be incomplete if the institution's clinical laboratory services were ignored. As noted previously, the JCAH has adopted new clinical laboratory standards and hospitals will be surveyed under these standards beginning in 1979.

The present construction of Sec. 373 of the Act provides that either the Federal Government or States may impose a maximum $500.00 laboratory licensure fee. This provision constitutes a distinct disincentive for clinical laboratories to participate in voluntary certification/accreditation programs. Such laboratories would be required to pay a fee for participation in a voluntary program recognized by the Secretary under Sec. 377 of the Act and could also be required to pay another periodic $500.00 fee for a Federal license.

RECOMMENDATIONS

That Sec. 373(a) be amended to provide that the Secretary may waive or prescribe variances in licensure fees for laboratories participating in voluntary certification/accreditation programs conducted by qualified public or nonprofit private entities.

AGREEMENTS AND ASSISTANCE

Section 377(a) of the Act could be interpreted as requiring qualified public or nonprofit private entities to enter into a contract with the Secretary to become the government's agent for purposes of inspecting clinical laboratories. Clearly, regulations implementing this legislation could require this. The JCAH, as a matter of principle, would not undertake surveys of hospital clinical laboratories as an agent of the government because of our board's position that participation in the JCAH program must be voluntary. A review of some of the history of this legislation suggests the intent that the JCAH accreditation program could provide an avenue for laboratory licensure.

Senator Javits, in his introductory remarks on S. 705 in the *Congressional Record* of February 10, 1977, stated that S. 705 would "authorize the Secretary and enforcing State to utilize the services of private, nonprofit entities for the provision of inspection and proficiency testing services."

From the Committee Report on S. 1737 (page 18), "The Committee is aware of the role that certain nationally recognized private nonprofit entities have played in the improvement of laboratory testing . . . Thus, this legislation provides that the Secretary, or a State where it has met or exceeded Federal standards, may enter into arrangements with qualified private nonprofit . . . associations for the provision of inspection . . . services . . . The programs of those qualified national organizations which meet or exceed the standards developed by the Secretary would be acceptable for meeting Federal and/or State Laboratory licensing requirements, and the government could enter into appropriate arrangements with such entities."

Mr. Chairman, the language of this section of the bill must clearly be changed if you wish to perpetuate voluntary programs of clinical laboratory certification/accreditation. There is nothing voluntary about an inspection conducted by an organization acting as an agent of the government.

RECOMMENDATIONS

That Section 377 be amended to provide that, in addition to the agreements presently provided for, the Secretary and States may make findings that clinical laboratories voluntarily participating in qualified public or nonprofit certification/acceditation programs meet federal licensure requirements.

H.R. 10909 TECHNICAL PROBLEM

You may wish to note that the proposed amendment to Section 1865(a) of the Social Security Act contained in Sec. 202(c) of H.R. 10909 does not appear to recognize the changes in Section 1865 effected by Section 234(h), PL 92–603.

Mr. Chairman, we appreciate this opportunity to express our views on the Clinical Laboratory Improvement Act of 1978.

STATEMENT OF DAVID C. SPRIGGS ON BEHALF OF THE NATIONAL ASSOCIATION OF ALLIED HEALTH SCHOOLS; THE AMERICAN ASSOCIATION OF COMMUNITY AND JUNIOR COLLEGES; AND THE AMERICAN VOCATIONAL ASSOCIATION

I am David C. Spriggs, president-elect of the National Association of Allied Health Schools which has historically been representative of a large segment of both private and public schools that train in such areas as Medical Laboratory Technician, Dental Laboratory Technician, and X-Ray Technician. These schools may be free standing institutions, departments of public junior colleges, departments of postsecondary vocational-technical schools, technical institutions, or units of hospitals. The school of which I am the Administrator is

the Georgetown School of Science and Arts here in Washington, D.C., an independent institution. Other examples of institutions offering educational programs of accredited or approved programs for technician personnel are:

Navarro College, Corsicana, Tex. (public junior college). Cumberland School of Medical Technology, Cookeville, Tenn. (independent institution). U.S. Department of Justice, Bureau of Prisons, Medical Center for Federal Prisoners, Springfield, Mo. (Federal). The Bryman School, Canoga Park, Calif. (independent institution). The Institute for the Advancement of Medical Sciences, Cherry Hill Medical Center, Cherry Hill, N.J., (hospital). North Georgia Technical and Vocational School, Clarksville, Ga. (public vocational-technical).

The graduates of these institutions are the products of a valid vocational training program generally leading to a legitimate educational credential. In most cases they have had Federal financial student assistance of grants, loans, and work-study authorized by Title IV of the Higher Education Act of 1965, as amended. (see Sections 435(a), 491(b) & 1201(a) for institutional definitions of eligibility.) Graduation as members of the allied health professions is related to both state licensure and professional registries.

The American Association of Community and Junior Colleges (AACJC) and the American Vocational Association (AVA) share the concern of NAAHS that the present version of H.R. 10909 does not recognize the training and education, made possible through federal and state funding, of technician personnel at less than bachelor degree levels. AVA is an association with 50,000 members and over 2,000 professional health occupations teachers. AACJC is an association of about 1,000 colleges. Community colleges are unique institutions with special responsibilities and goals, including the training and education of persons for technician level employment in the allied health professions.

Although the roles of clinical laboratory personnel may vary depending upon the level and type of training, all laboratory practitioners including technicians contribute to the performance of scientific analyses to provide the medical community with data upon which to base decisions concerning the diagnosis and treatment of disease. The absence of accurate data greatly diminishes the physician's ability to deal with the many medical decisions necessitated in his mission to provide quality care to his patients.

This important principle has been firmly established under the Medicare program for the last decade. Under its Conditions of Coverage of Services of Independent Laboratories Medicare has adopted qualification standards for all laboratory personnel including the technician level.

As written, H.R. 10909 proposes to eliminate qualification standards for laboratory technicians and substitute in their place the requirement that supervisory personnel, through periodic practical examinations, evaluate the proficiency of technicians employed in laboratories.

Without belaboring the point that such evaluations will largely be based upon differing interpretations made by individuals who must answer to superiors who, due to economic considerations, may not always have the best interests of the patient in mind, it is clear that the current language contained in H.R. 10909 does not provide sufficient guarantees to assure the competency of technician work. Unfortunately, the current provisions actually act as an incentive for laboratories to hire individuals without any laboratory training and pay them accordingly.

This legislation fails to recognize the fact that many qualified technician personnel are being trained in numerous institutions accredited by agencies recognized under the statutory authority of the U.S. Office of Education. In fact, personnel who are properly trained would be treated in the same exact manner under H.R. 10909 as individuals who were literally taken off the streets to work in a laboratory. Because prior education and experience is not recognized at the technician level as a basis for qualification under the proposed bill the incentive for any individuals to obtain an appropriate training background would be markedly decreased. This situation is both unjust and inequitable to the many qualified technicians that would be affected by this provision. The real losers unfortunately would be the American public who are not being given sufficient guarantees regarding the competency of technician personnel performing diagnostic laboratory tests.

Mr. Chairman, we are not suggesting that the only individuals permitted to work as laboratory technicians should be those who have completed a struc-

tured training program. What we are saying however, is, let's recognize those individuals who are properly trained like we do throughout the rest of the health care system and provide alternative qualification routes such as proficiency or practical examinations for other personnel who wish to qualify.

ABILENE, TEX., *May 3, 1978.*

Congressman OMAR BURLESON,
Congress of the United States,
House of Representatives,
Washington, D.C.

DEAR CONGRESSMAN: The days of tenure as the representative of the "Big Country" in Washington are now drawing to a close. We of this district have been the envy of the other real Americans of our country. I can assure you that as I contact professional people, independent farmers and ranchers, and small business men, they know who you are and what you have stood for these many years while you served in that maze on the Potomac.

I write you now for assistance in altering or killing some particularly obnoxious sections of H.R. 10909, also known as the Clinical Laboratory Improvement Act of 1978. It seems that as a problem arises in New York or New Jersey—a reaction begins that sweeps the entire country without regard to our way of life out here at the edge of the Great American Desert.

H.R. 10909 on page 11, line 5 begins to describe some exceptions to "national standards" for the laboratory. I really don't understand why! I don't understand why all doctors offices were exempted from these laboratory standards, if the goal of the Clinical Laboratory Improvement Act is to improve the quality of laboratory results. At this time, however, doctors office laboratories are still exempted. Tests can be run by office clerical help—by individuals with no laboratory training at all. Now H.R. 10909 wants to exempt cardiac laboratories and pulmonary function laboratories from these standards. Anyone in the field of medicine can see that one could include practically every human pathology laboratory test under cardiac laboratory testing—for the human body is not that compartmentalized. Cardiac function could include the analysis of serum potassium, a very critical element in cardiac function—ah, but these is also calcium, sodium, carbon dioxide, chloride—all the electrolytes. Any number of enzymes such as creatine phosphokinase or lactic dehydrogenase relate to cardiac damage. Everyone knows that as the heart fails, other organs may follow—kidney, liver, lung, etc. I need not expand this argument further for cardiac nor for pulmonary function laboratories. You can see quite easily what a can of worms this could become. A hospital could split up the clinical laboratory into twenty or thirty independent small "specialized laboratories and avoid any national standards whatsoever. This could be carried even to the ridiculous, such as having a laboratory purely for measuring blood hemoglobin. One could see quite easily that this would raise the cost of operation, for each one of these specialized laboratories would have to have twenty-four hour coverage.

It would make administration most difficult and all but completely destroy any medical technology training programs in the institutions.

Page 46 of HR–10909 lists the "need for competitive bidding of laboratory services". I can only see Revlon (the cosmetic company is also in the pathology laboratory business), Abbott or Smith, Kline and French (yes, large drug companies are in the pathology laboratory business)—or even some other large national company (what is to prevent General Motors from getting involved?) to be bidding for this business and thus destroying what little coverage we can provide here in the boondocks. These large national laboratories are fully automated and run multichannel machines twenty-four hours a day. They operate courier services (auto and aircraft) and have full-time sales force with door-to-door solicitation. If they take away what little high volume automated work we get and leave us only with stat analysis, then our laboratories will collapse and we will have to get out of that part of medicine for which we have had great interest for these many, many years. Or there is another possibility—we would have to raise the cost of these stat procedures to unheard of levels. We pathologists in the outer areas of our State travel to surrounding small towns to do frozen section diagnosis on pathology specimens for surgeons. We also perform autopsies—medical and medicolegal—for these small communities. We perform these services where we are also receiving other laboratory samples for

testing, i.e., these lab tests subsidize the other services. If we lose this, then will Revlon give the onsite frozen section testing and will they also give the courtroom testimony in murder trials? I don't believe the intent of this bill should be to destroy the profession and turn it over to large multinational corporations. We are concerned about where the competent stat laboratory test will operate. Will we have to ship these samples to St. Louis (because Smith, Kline & French was the low bidder and have their laboratory located in that city)—and wait until the test is run? No, you will have to have some type of local testing, but at what price? Will patients have to travel to several places within a city to get their blood drawn because Medicare would pay for some tests only if drawn at certain localities but not at others?

There is also a move afoot at HEW to limit payment of Medicare patients to only the twelve most common laboratory tests. If a thirteenth was ordered, would we hold that until the patient could get cash to pay for it—or would we send in an application for exception to Washington, D.C.? It is true that pathologists are medical doctors and as physicians we could start seeing patients directly and start some type of service to feed the laboratories that we operate. However, that in itself would not be solving some of the problems that exist between the laboratory and the clinician. Clinical pathology is the liaison between the analyst in the laboratory and the clinician. This liaison should not be destroyed. Numbers determined by analysts are given to the clinician who is aware of the signs and symptoms of the disease that he is studying. There must be some type of association between the two to determine appropriateness of the tests and the value of the numbers that were obtained. This is the role of the clinical pathologist. It must be someone who has both knowledge of the analytical aspects and of the clinical problem. Laboratory personnel who have no medical training cannot appreciate the problems in medical diagnosis and treatment.

Blind testing: This part of HR–10909 presents untold problems and they have been commented on by experts frequently in the past. It just isn't practical on a wide scale basis. I see nothing wrong in some type of intensified blind testing for laboratories suspected of fraud. I believe there should be proper safeguards to prevent harassment by unscrupulous inspectors who themselves may be unqualified.

How do you get a blind sample into a hospital? We draw the samples from the patients ourselves.

How do you get a blind sample into a private laboratory? You would have to have one of our employees or the referring doctor in on the plan. If the results of the test were abnormal, we would naturally call the physician and ask for additional information about the history and physical examination of the patient and might suggest a repeat sample being drawn. I don't know, but this could imply some fraud on the part of the U.S. government itself if they were a party to this.

How could you make sure the sample you sent to the laboratory was handled in such a way or be of such quality as to render a duplicate test by the referring governmental service as the absolute value?

Some tests are not done everyday in all laboratories; this adds some problems to this procedure.

How could you keep the chain of evidence intact? The laboratory being tested may want to have the reference sample tested by another independent laboratory before they would accept the government value.

We are all aware of the level of proficiency in Veterans Administration hospitals—would they also be tested as well?

There are many attacks from several sources on laboratory medicine. Some of these are not referred to in HR–10909. There is a move afoot to have Medicare within Texas to pay based upon the lowest price available in a community for that test. I see that this will cause nothing but further shortchanging of quality testing and/or the patient paying a higher price for the quality work.

Summary: I could go on at great length, but my voice is breaking as I dictate, and I know that you are certainly tired of reading this rather lengthy epistle. I think much more of this detail can be handled by Norman Burch who is a representative of a College of American Pathologists and is located in an office there in Washington, D.C. I would appreciate it if you could speak with Norman. His office is located at 1775 K Street Northwest, Washington, D.C. 20006, and his telephone number, 202–466–4112,

The pathologists here in Abilene and your district will be most appreciative of anything you can do with regards to these many, many problems. I am sorry I missed seeing you on your last trip to Abilene, but congratulations on your new honorary degree, and we will be looking forward to seeing you the next time you come West.

Yours truly,

B. B. TROTTER, M.D.

Enclosure.

[From Laboratory Management, April 1978]

STRENGTHS IN NUMBERS: THE NEEDED TREND FOR INDEPENDENTS

HOW MUCH OF A CHANGE DOES THE "LITTLE GUY" HAVE TO SURVIVE TODAY?

Some of the things that are obvious when one looks at the clinical laboratory situation in this country is that equipment is getting larger, more sophisticated, and more efficient. Unfortunately, it is also becoming more expensive.

One positive offshoot of this, however, is that costs of the individual lab tests themselves are actually going down! Twenty years ago doctors were being billed $3 to $5 for a blood sugar. With today's multiple SMAC profile capabilities, this same blood sugar is now 50¢ to $1 per test. And it is my belief that these revolutionary hardware advances in laboratory medicine have had a tremendous effect in one main area: our collective ability to deliver a higher quality of health care.

With the availability of low-cost multiple testing, diseases are being recognized more frequently when there are no apparent overt symptoms. And as technological advances continue, I can foresee the day when 100 or even 200 test profiles are common. At this point, each patient will have his or her own individual set of norms established and disease will be more quickly and easily recognized by variations in the norms of that patient. Example: If a patient has a uric acid of 3.5, he will probably have a uric of 3 to 5 for many years. But suddenly it jumps to 7. Although this figure is still within "normal" parameters, it is in fact abnormal for that particular patient based on his already established normal trends. Evaluation of sudden changes in an individual's normal trend line may be the earliest indication of subclinical disease. This has important implications for preventive medicine. But the cornerstone of this type of high quality health care has to be the evolution of low cost, high volume trending capabilities. Not just for standard procedures, but for more esoteric testing such as urinary estrogens.

No one really knows how urinary estrogens fluctuate in a large population on a continuous basis. There is much controversy as to whether or not estrogens protect women against such major disorders as heart attacks, bone deterioration, and aging changes. Yet, we rarely do estrogens, certainly not on a continuous basis, because of the high cost of the procedures. However, if an estrogen cost $2 or $3, one wouldn't hesitate to do one on every woman and monitor it, again, with trending. Data potentially gleaned from this type of ongoing normative scrutiny of laboratory parameters could have staggering implications, because they relate to the ramifications of bodily functions we are only dimly aware of.

Let us now address ourselves to trends relating to the small-to-medium-size laboratory owner. With current government regulation being placed on greater efficiency and less waste, there is no doubt in my mind that there is going to be a crunch, which will occur at the laboratory level in terms of costs.

Here in New York City, for example, the government has started to play a greater regulatory role because of the city's growing number of Medicaid patients. And even though Medicaid lab fees were *already* lower than other lab fees, the City government arbitrarily decreed to cut these Medicaid test fees in half. The net result was obvious: A significant number of laboratories already operating at a minimal profit margin and highly dependent on Medicaid patients were put out of business.

The small-to-medium-size laboratory's problems are further compounded by sheer economics. Most couldn't begin to afford an SMA–12, SMA–20, or the autochemist from Sweden which some utilize to perform 25 tests automatically. Competing with hardware that can produce a 24-test profile for approximately $7.50 puts the smaller laboratories in an impossible situation. Their reagent cost itself, let alone manual labor and overhead, is such that the "little guy" just doesn't have a chance. The costs involved to perform a SMAC-20 profile manually would be a minimum of $8–$10.

It is not beyond the realm of possibility to envision the 20,000 or so clinical laboratories in this country dwindling down to 100 . . . 50 . . . 10 . . . or maybe even to "The Big Three," as in the auto industry. The implications of this concept are frightening. The need for the continuance of local laboratories is imperative.

Communities without local laboratory facilities would find that Stat service would disappear, and patients would have to travel distances to be tested when the time that the sample is taken is of importance in the accuracy of the test results. Also, without local laboratories, distant laboratories could not respond physically or logistically to the health needs of the community and expectations of any semblance of reasonable price competition disappears. Thus, the quality of health care in this country would, of necessity, suffer. These two aspects alone definitively state the need for local labs to survive as part of an efficient health care system and as a safeguard to the public welfare.

Based on my experience as a physician involved in the daily care of critically ill patients and as a laboratory director, I suggest serious efforts be made to guarantee the survival of local laboratories.

GOVERNMENT REGULATION

I believe government regulation should encourage rather than impede, localized ownership of laboratories. I think, for example, that some of the pending regulations for local labs do not take into account varying conditions in personnel in different areas of the country. There are regulations pertaining to lab directors, supervisors and levels of qualification for laboratories with three or four people which are quite similar to regulations pertaining to labs with 100 or 200 people. If such regulations were followed to the letter, they would necessitate the closing of many laboratories, thus leaving sections of the country without local laboratory service. Unless additional criteria are taken into account, existing regulations will only accelerate small laboratory extinction.

In the area of quality control, I urge that less emphasis be placed on management and supervisory qualification requirements and more emphasis be placed on the technologists and technicians who actually perform the tests. In addition, provision must be made for local on-the-job training. It is important that artificial educational criteria do not prevent entry to or advancement in the laboratory field of otherwise qualified personnel. This is particularly important to minority groups who often have an inferior educational background but are still capable of good performance levels with on-the-job training. The highest standards of strong quality control should, of course, remain mandatory.

There can be no shortcuts when it comes to performance of independent testing. This should be the main criteria for evaluating local laboratories, namely, to prove that they can perform tests commensurate with the highest standards of quality control.

INDUSTRY ORGANIZATION

Organizational stances should be adopted so that local laboratories can survive. Of prime importance is instituting an aggressive, organized effort to strongly voice industry opinions and postures. The most glaring example of what can happen in the absence of strong lobbying efforts is found in what began as the Kennedy-Rogers Bill, wherein is stated that certain laboratory procedures performed in physician's offices are exempt from meeting the qualification requirements standard clinical labs must adhere to. This is a blatant double standard which is totally untenable. I basically feel that all laboratories should participate in independent quality control programs. A physician should have the right to have his own laboratory in his office. However, the lab should participate in the same quality control programs as any other laboratory, meet the same personnel requirements, and so forth. The main point is that current laboratory legislation will have the effect of accelerating the demise of the small independent laboratory which is regulated by quality control while leaving untouched the local in-office laboratory which has the lowest level of quality control. One local laboratory serving 50 physicians is in a much better position to provide proper quality and personnel at a reasonable charge than 50 separate laboratories.

A second aspect of potential industrywide organization has many precedents. It is simply the group association concept. The supermarket industry, the hardware field, the farm cooperatives, all grew strong and more efficient by using the strength of their numbers. Although this concept may not be the panacea for all organizational ills of the industry, it could be the impetus to forming a powerful organization to make lawmakers aware of the problem unique to the industry and hence influence forthcoming legislation. If properly implemented, volume purchasing power and a system of centralized, non-competitive reference could be proffered as well, to enable small independents to at least co-exist with the "giants."

As a concerned professional, I feel that some action, whatever it is, must be taken by small clinical labs if they are to survive.